UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

BULLHEAD CITY, ARIZONA,

Plaintiff,

vs.

ACTAVIS, INC.; ALLERGAN PLC; ACTAVIS PLC; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; ; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JOHNSON & JOHNSON; JOHN KAPOOR, an individual; MICHAEL BABICH, an individual; MCKESSON CORPORATION; CARDINAL HEALTH, INC.; AMERISOURCEBERGEN; and DOES 1 through 1000,

Defendants.

MDL 2804

Case No. 1:17-md-2804-DAP

Member Case No.

Judge Dan Aaron Polster

COMPLAINT AND JURY DEMAND

I. INTRODUCTION

1. Opiates[1] are killing people every day in this country and Arizonans have not

[1] The term "opiate" technically refers only to chemicals that occur naturally in the opium plant, including morphine, codeine, thebaine and papaverine. "Opioid," by contrast, refers instead to compounds that have the same effect as opiates but do not occur naturally in the opium plant, such as heroin, oxycodone, hydrocodone, hydromorphone and oxymorphone ("semi-synthetic" opioids) as well as methadone, fentanyl, meperidine and tramadol

been spared. Each of the Defendants in this action engaged in an industry-wide effort to downplay the dangerous and deadly potential effects of the misuse of prescription opioids. The opioid epidemic has hit every community in Arizona hard, including Bullhead City. Bullhead City brings this complaint seeking redress for the societal and financial damage it has suffered at the hands of those directly responsible for the crisis—the manufacturers and distributors of prescription opioids.

2. This case is about corporate greed. Simply put, each of the Defendants put its desire for profits above the health and safety of Bullhead City's residents. Bullhead City and its citizens have paid dearly as a result.

3. This case is not about taking away medically necessary opioids from the patients who need them. Plaintiff does not ask the Court to decide whether opioids are clinically appropriate, nor does Plaintiff seek to blame the well-meaning healthcare providers and suppliers who prescribed opioids to their patients in good faith. Instead, Plaintiff only asks that this Court hold the Defendants accountable for the damage they caused to Bullhead City that Defendants were always in the best position to prevent.

A. The Manufacturer Defendants' Two-Part Scheme to Increase Opioid Sales

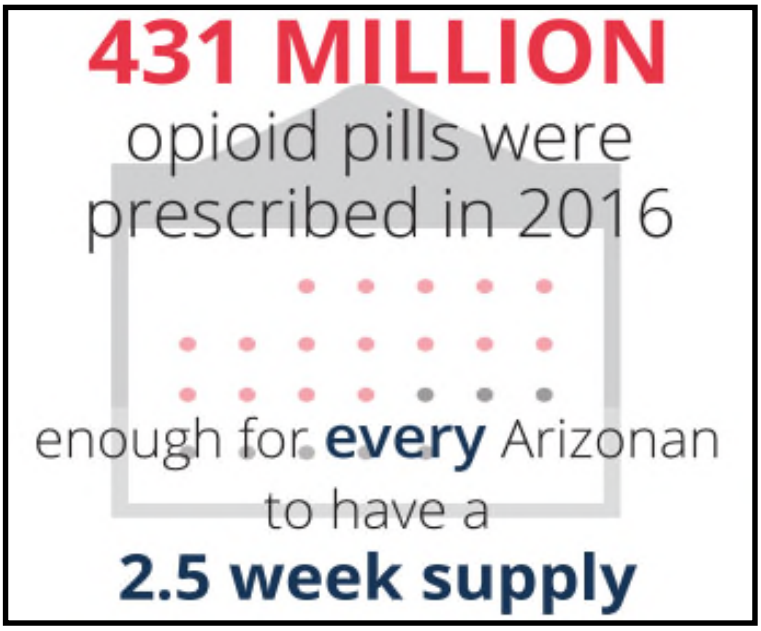
4. First, as part of a broader scheme to target all municipalities in the United States where the elements most conducive to opioid addiction were prevalent, Defendants ALLERGAN PLC; ACTAVIS PLC; ACTAVIS, INC.; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN

("synthetic" opioids).

PHARMACEUTICALS, INC.; JOHNSON & JOHNSON; and the individual defendants JOHN KAPOOR and MICHAEL BABICH ("the Manufacturer Defendants"), targeted the State of Arizona, including the residents of Bullhead City. More specifically, the Manufacturer Defendants developed and engaged in a sophisticated, manipulative marketing scheme designed to increase the number of opioid prescriptions written across the state, including in Bullhead City. Defendants' scheme was particularly well-suited to Bullhead City, because it is home to a multitude of economically and medically vulnerable populations that Defendants knew were uniquely predisposed to opioid addiction, including the elderly. It is currently estimated that 29.2% percent of Bullhead City's population is comprised of senior citizens.[2]

5. Second, while the Manufacturer Defendants knew their opioids were unsafe and ineffective for treating chronic pain, they worked together to unlawfully increase their profits and sales in Bullhead City by (1) repeatedly misrepresenting the safety and effectiveness of prescription opioids for the long-term treatment of chronic pain; (2) concealing from Bullhead City and the public the true risks and benefits of long-term opioid therapy for chronic pain; and (3) pressuring their respective sales forces to deceive (even bribe) local prescribers to flood Arizona—and Bullhead City—with enough opioid prescriptions for every single person in Bullhead City.

[2] U.S. Census Bureau QuickFacts, *Bullhead City*, available at https://www.census.gov/quickfacts/fact/table/bullheadcitycityarizona/PST045218



6. In doing these things, the Manufacturer Defendants and their employees and associates (the "RICO Marketing Participants")[3] intentionally and knowingly designed, implemented and directed a common course of conduct, forming an association-in-fact enterprise (the "Opioid Marketing Enterprise") with a simple purpose: to ensure the RICO Marketing Participants succeeded in illegally increasing their sales and profits across the country, including in Bullhead City.

B. The Distributor Defendants Turned a Blind Eye to the Manufacturers' Scheme

7. Defendants MCKESSON CORPORATION, AMERISOURCEBERGEN and CARDINAL HEALTH, INC. (the "Distributor Defendants") shipped prescription opioids throughout the country, including to addresses in Bullhead City. Rather than meet their obligations to report suspicious orders of opioids, the Distributor Defendants willfully ignored impossibly large orders shipped into locations where it was inconceivable that any legitimate medical need could have required the quantities shipped. They failed to report these suspicious shipments despite their clear statutory and common law obligations to do

[3] The RICO Marketing Defendants include the Manufacturer Defendants, as well as Individual Defendants Babich and Kapoor, and unnamed co-conspirator McKinsey.

so, and in contravention of their own internal policies and procedures. The Distributor Defendants' breaches of their respective reporting obligations were willful, motivated by their desire to maximize profits, and were committed without consideration of the cost to Bullhead City or its citizenry.

8. For over a decade, the Distributor Defendants and certain other (the "RICO Supply Chain Participants")[4] have worked together to build an illicit, association-in-fact enterprise (the "Opioid Supply Chain Enterprise"), intended to unlawfully increase their prescription opioid sales by fraudulently increasing the quotas set by the Drug Enforcement Administration ("DEA"). In furtherance of this scheme, the RICO Supply Chain Participants intentionally and knowingly disseminated false and misleading statements to regulators, used their political clout to halt investigations by the DEA and the Department of Justice ("DOJ"), and committed thousands of other acts with the specific intent to advance their illegal scheme.

A. The Devastating Effects of Defendants' Conduct

9. Each of the Defendants was fully aware that its products placed patients at an unreasonable risk of opioid-related addiction and/or death. Despite this knowledge, the RICO Marketing Participants continue to misrepresent the risks associated with prescription opioids and their efforts to influence physicians with the goal of increasing sales of prescription opioids to the nation at large, as well as to Bullhead City's most vulnerable citizens.

10. Likewise, the RICO Supply Chain Participants continue to breach their legal duties to monitor, report, and prevent suspicious shipments of prescription opioids. This conduct precipitated the opioid crisis that has ravaged Plaintiff's communities since the early 2000s, and will continue to do so for many years, even decades, to come.

11. Defendants' scheme has succeeded—they have made untold billions of dollars from misrepresenting the risks and benefits of prescription opioids for the long-term

[4] The RICO Supply Chain Participants include Manufacturer Defendants; Distributor Defendants; and unnamed co-conspirator McKinsey.

treatment of chronic pain. Meanwhile, the death toll they have caused in Bullhead City and elsewhere is unconscionable.

12. Bullhead City dedicates substantial portions of its tax revenues to provide and pay for a broad array of services for its population, including health care, pharmaceutical care, law enforcement, foster care, public assistance and other necessary services and programs for families and children. However, as a result of the opioid epidemic, Bullhead City has been severely hampered in its ability to continue to provide the requisite level of service in each of these categories. This creates a perverse dichotomy. The overburdened service areas require a *greater share* of its scarce tax dollars, while at the same time, the crisis itself *decreases* the tax dollars Bullhead City can generate. That is because opioid addiction takes productive members of society out of the economy, usually due to death or the inability to work. Simply put, most who become addicted to opioids are no longer able to work, and therefore are no longer able to care for their families, earn a paycheck or spend money in the same way they did before they fell victim to addiction. This relentless downward spiral means Bullhead City's tax revenues have suffered. These harms are the direct and proximate result of Defendants' scheme to increase their profits without regard for the end users of Defendants' drugs, or the municipalities that must bear the brunt of the increased demand for their services brought on by the epidemic.

13. In addition to its tax-related damages, Bullhead City, a thriving community of recreation and tourism located on the southern border of Lake Mohave, has suffered irreparable damage to its reputation at the hands of Defendants. This is due, in large measure, to press surrounding the opioid epidemic in Mohave County and the "tri-state area" which includes Fort Mohave, Mohave Valley and Bullhead City, Arizona, as well as Laughlin, Nevada and Needles, California.

14. Bullhead City has been able to ameliorate this problem, to a degree, only by dedicating substantial—and previously unallocated—tax dollars to measures designed to restore its once sterling reputation as one of the most desirable communities in all of Arizona. As one example, on or about September 8, 2018, Bullhead City hosted an opioid symposium

at Mohave Community College. Speakers included care providers, nonprofit groups, addiction specialists, and law enforcement and court representatives. The symposium focused on the importance of collaboration and partnerships in helping people solve their addiction problems.

15. Things were not always this way in Bullhead City. Though Defendants have been manufacturing, marketing, distributing, and selling prescription opioids for decades—including brand-name drugs like OxyContin, Percocet, Endocet, Vicodin, Zydone, Dilaudid, Duragesic, Methadose, Sublimaze, Actiq, Fentora and Nucynta, as well as generic formulations such as oxycodone, hydrocodone, hydromorphone, methadone, fentanyl and tapentadol—only since the late 1990s have Defendants' powerful narcotic painkillers been used to treat more than just short-term, acute or cancer-related pain. Indeed, for the vast majority of the twentieth century, Defendants' drugs were considered too addictive and debilitating for patients suffering from long-term (chronic) pain due to non-cancer conditions like arthritis, fibromyalgia and migraines.[5]

16. In the late 1990s, however, and continuing today, Defendants began a sophisticated marketing and distribution scheme premised on deception to persuade patients that opioids can and should be used to treat long-term chronic pain. Defendants spent, and some continue to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids and overstate the benefits of opioids. As to the risks, Defendants falsely and misleadingly: (1) downplayed the serious risk of addiction;[6] (2) promoted the concept of "pseudoaddiction," falsely claiming that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in

[5] In this Complaint, "chronic pain" means non-cancer pain lasting three months or longer.

[6] Addiction is classified as a spectrum of "substance use disorders" that range from misuse and abuse of drugs to addiction. Patients suffer negative consequences wherever they fall on this spectrum. In this Complaint, "addiction" refers to the entire range of substance abuse disorders. (*See* American Society of Addiction Medicine Public Policy Statements: https://www.asam.org/docs/default-source/public-policy-statements/1-terminology-spectrum-sud-7-13.pdf?sfvrsn=d93c69c2_2.)

preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of abuse-deterrent opioid formulations to prevent abuse and addiction by—*inter alia*—misrepresenting that these opioids "cannot be crushed." Defendants also falsely touted the benefits of long-term opioid use, including its supposed ability to improve function and quality of life, even though there was no good evidence to support those benefits—a fact that Defendants not only knew at all times relevant to this action, but further suppressed and concealed.

17. Indeed, at all relevant times, Defendants knew their longstanding and ongoing misrepresentations of the risks and benefits of opioids were not supported by, or were directly contrary to, the scientific evidence. Indeed, the U.S. Food and Drug Administration ("FDA") and the Centers for Disease Control and Prevention ("CDC") have recognized the serious risks posed by opioid pain medications, as evidenced by the CDC Guideline for Prescribing Opioids for Chronic Pain, which the CDC issued—and the FDA approved—in 2016 ("2016 CDC Guideline").[7] Opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc., Janssen Pharmaceuticals, Inc. and Cephalon, Inc.,[8] as well as

[7] *See generally* Deborah Dowell, MD, *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, CDC.gov (Mar. 18, 2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htmhttps://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

[8] *See* Department of Justice ("DOJ") – Office of Public Affairs, *Johnson & Johnson to Pay More Than $2.2 Billion to Resolve Criminal and Civil Investigations*, Justice.Gov (Nov. 4, 2013), available at www.justice.gov/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations; *see also* John George, *Endo pays $193M to settle off-label marketing of pain patch*, Philadelphia Business Journal (Feb. 21, 2014), available at https://www.bizjournals.com/philadelphia/blog/health-care/2014/02/endo-pays-192m-to-settle-off-label.html; *see also* Government's Memorandum for Entry of Plea and Sentencing, *U.S. v. Cephalon, Inc.*, Justice.Gov (Sep. 14, 2016), available at https://www.justice.gov/sites/default/files/cases/attachments/2016/09/14/cephalon_sentencing_memorandum.pdf.

Mallinckrodt and Purdue Pharma L.P.[9] have also entered into agreements[10] with public entities that prohibit them from making many of the misrepresentations identified in this Amended Complaint in other jurisdictions. Yet, even now, Defendants continue to misrepresent the risks and benefits of long-term opioid use in Arizona, including in Bullhead City, and continue to fail to correct their past misrepresentations.

18. Specifically, the RICO Marketing Participants worked together to conceal what their own internal documents and communications show they already knew, and had known for decades: not only were Defendants' opioids both medically unnecessary and, in fact, life-threatening for non-cancer patients with chronic pain, but further, none of the RICO Marketing Participants' representations about the manageability or prevention of opioid addiction was true. As set forth in detail below, for decades the RICO Marketing Participants have made and continue to make a series of inaccurate claims about the risks and benefits associated with their opioids, essentially bribing Key Opinion Leader ("KOL") group to substantiate the veracity of Defendants' false statements and intentionally submitting false reports to regulators to conceal their misconduct.[11] In creating the illusion that prescription

[9] Mallinckrodt and Purdue have declared bankruptcy and are not defendants in this action, and any allegations herein describing their misconduct are purely contextual. *See* Opinion and Order, *U.S. v. Purdue Frederick Company, Inc., et al*, No. 1:07CR00029 (July 23, 2007), available at www.vawd.uscourts.gov/OPINIONS/JONES/107CR00029.PDF; *see also* Department of Justice – Office of Public Affairs, *Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations*, Justice.Gov (July 11, 2017), available at www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

[11] *See, e.g.*, Attachment B to Plea Agreement in *United States v. The Purdue Frederick Co., Inc.*, Case No. 1:07-cr-00029-JPJ: Purdue Agreed Statement of Facts, ("PASF") at ¶¶ 26, 29. ("[s]ome of Purdue's new sales representatives were permitted . . . to draw their own blood level graphs to falsely represent that OxyContin, unlike immediate-release or short-acting opioids, did not swing up and down between euphoria and pain and resulted in less abuse potential"; and "[o]n or about May 1997, certain Purdue supervisors and employees stated that [while] they were well aware of the incorrect view held by many physicians that Oxycodone was weaker than morphine, they did not want to do anything 'to make physicians think that Oxycodone as stronger or equal to morphine' or to 'take any steps in the form of

opioids were a low risk treatment option for chronic pain relative to nonopioid pharmacologic approaches, Defendants successfully targeted vulnerable patient populations like the elderly. The RICO Marketing Participants further tainted the sources that doctors and patients in Bullhead City relied upon for guidance, including treatment guidelines, continuing medical education programs, medical conferences and seminars, and scientific articles. Through these and thousands of other misdeeds, the RICO Marketing Participants successfully transformed the way doctors treat chronic pain in Bullhead City.

19. Similarly, the RICO Supply Chain Participants illegally increased their profits and revenues from opioid sales in Bullhead City by, among other things, fraudulently increasing the mandatory quotas set by the Drug Enforcement Administration ("DEA") and intentionally frustrating regulators' efforts to investigate and stop the RICO Supply Chain Participants' misconduct. As detailed below, the RICO Supply Chain intentionally failed to report suspicious opioid transactions to regulators, repeatedly provided regulators with bogus reports that falsely and misleadingly claimed the RICO Supply Chain Participants were properly monitoring and reporting suspicious opioid transactions, and—if these tactics failed—the RICO Supply Chain Participants would simply leverage their vast political influence to extinguish regulatory investigations of their misconduct before they could get off the ground.

20. The RICO Marketing Participants and the RICO Supply Chain Participants' systematically deceptive conduct has ravaged Bullhead City's communities, opening the floodgates of opioid prescribing and use and foreseeably creating an illicit opioid market in Bullhead City.

21. This explosion in opioid prescriptions and use has padded Defendants' profit margins at the expense of chronic pain patients. As the CDC recently concluded, "for the vast majority of [those] patients, the known, serious, and too-often-fatal risks far outweigh

---

promotional material, symposia, clinical publications, conventions or communications with the filed force that would affect the unique position that OxyContin had in many physicians' minds' ").

the unproven and transient benefits."[12]

22. The explosion in opioid prescriptions and use caused by Defendants has led to a public health and safety crisis in Arizona, including in Bullhead City. Arizona faces skyrocketing opioid addiction and opioid-related overdoses and deaths as well as devastating social and economic consequences. This public health and safety crisis is a public nuisance because it "is injurious to health" and interferes "with the comfortable enjoyment of life and property" (A.R.S. § 13-2917(A)) and because it affects "entire communit[ies]" and "neighborhood[s]" and "any considerable number of persons" (*Id*.) The effects of Defendants' deceptive marketing scheme are catastrophic and are only getting worse. These effects are devastating in Arizona. More than two Arizonians die each day from an opioid overdose. There has been a 74% increase in deaths among Arizona residents since 2012. As the FDA acknowledged in February 2016, "[t]hings are getting worse, not better, with the epidemic of opioid misuse, abuse and dependence."[13]

23. There is little doubt that RICO Marketing Participants' deceptive marketing campaigns, and RICO Supply Chain Participants' illegal distribution scheme, have precipitated this public health and safety crisis in Arizona, including in Bullhead City, by dramatically increasing opioid prescriptions and use. An oversupply of prescription opioids has provided a source for illicit use or sale of opioids (the supply), while the widespread use of opioids has created a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or legitimately obtain opioids, they often turn to the street to buy prescription opioids or even heroin.

24. Defendants' deceptive marketing and distribution scheme have had further foreseeable impacts on Bullhead City. As a result of Defendants' conduct, Bullhead City must devote increased resources to the burden of the addicted homeless who commit drug

---

[12] Thomas R. Frieden et al., *Reducing the Risks of Relief — The CDC Opioid-Prescribing Guideline*, 374 New Eng. J. Med. 1501-1504 (2016).

[13] FDA.gov, *Califf, FDA top officials call for sweeping review of agency opioids policies*, U.S. Food and Drug Administration ("FDA") News Release (Feb. 4, 2016), http://www.fda.gov/ NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm.

and property crimes, to feed their addiction. For example, tax dollars are required to maintain public safety of places where the addicted homeless attempt to congregate, including parks, schools and public lands. Tax dollars are required to fight the infectious disease brought by the addicted and particularly the addicted homeless. Hepatitis B and C, HIV, sexually transmitted disease and methicillin-resistant Staphylococcus aureus ("MRSA") have been demonstrated to be spread by opioid abuse.

25. Defendants' willful and wrongful conduct has further impacted Bullhead City by creating a public nuisance in Bullhead City that Defendants foresaw yet deliberately ignored. Defendants were aware at all relevant times when they deceptively marketed their products as non-addictive that such addiction would be highly difficult to overcome.

26. The role of Defendants' deceptive marketing and distribution scheme in causing this public health and safety crisis has become well-recognized in recent years. In her May 2014 testimony to the Senate Caucus on International Narcotics Control on behalf of the National Institutes of Health ("NIH"), Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."[14] In the years since her comments were initially published, Dr. Volkow's message has become the dominant view of the top experts and influencers in the medical community, who are finally realizing just how dangerous Defendants' opioids are, and how devastating the economic and social costs of Defendants intentional deception has been.[15]

27. Absent RICO Marketing Participants' deceptive marketing scheme and RICO Supply Chain Participants' fraudulent distribution practices, the opioid use, misuse, abuse, and addiction in Bullhead City would not have become so widespread, and the opioid

[14] N. Volkow, M.D., *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, National Institute on Drug Abuse, (May 14, 2014), available at: https://www.drugabuse.gov/about-nida/legislative-activities/testimony-tocongress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse.

[15] E. O'Brien, *Here's What it Would Cost to Fix the Opioid Crisis, According to 5 Experts*, Time Money (Nov. 27, 2017), http://time.com/money/5032445/cost-fix-opioid-crisis/

epidemic that now exists in Bullhead City would have been averted or much less severe.

28. By falsely downplaying the risks and grossly exaggerating the benefits of long-term opioid use through their deceptive marketing claims despite their knowledge of the falsity of those claims, and by improperly distributing, compounding and dispensing prescription opioids as set forth herein, Defendants have not only engaged in false advertising and unfair competition, but they have also created a public nuisance, as well as violated the Racketeer Influenced And Corrupt Organizations Act, 18 U.S.C. § 1962(c)-(d) ("RICO"). Although the majority of detailed allegations herein centers on Defendants' misconduct during the past six years, every act of malfeasance committed by each Defendant since the late 1990s as part of its deceptive marketing and distribution scheme subjects that Defendant to liability for both RICO and public nuisance (for which there is no statute of limitations). (See A.R.S. § 13-2917(A).).

29. Accordingly, Defendants' ongoing misconduct, both individually and collectively, has violated and continues to violate Arizona's Public Nuisance Law, A.R.S. § 13-2917. It also constitutes "racketeering activity" under 18. U.S.C. § 1961(5). Bullhead City does not ask this Court to weigh the risks and benefits of long-term opioid use, and instead seeks an order requiring Defendants to cease their unlawful promotion and of prescription opioids; to correct their misrepresentations; and to abate the public nuisance they have created. In order to redress and punish Defendants' previous and current violations of law that cause and continue to cause harm to Bullhead City, Bullhead City also seeks a judgment requiring Defendants to pay compensatory damages, punitive damages, exemplary damages, and any fees or costs permitted under law, in an amount to be determined at trial.

30. By this action, Bullhead City further seeks to recoup tax dollars spent already for the consequences of Defendants' wrongful conduct in causing the opioid epidemic and crisis and its impact on Bullhead City, and to abate the opioid nuisance so Bullhead City will not be required to spend further taxpayer dollars on the epidemic and crisis wrought by Defendants.

II. PARTIES

A. Plaintiff

31. Bullhead City, Arizona, by and through its attorneys hereto and working in conjunction with its City Council, hereby brings this action to protect the public from an ongoing health and safety crisis.

32. Bullhead City is a city in Mohave County, Arizona. The population of the city is just under 40,000. Bullhead City has been referred to as "Arizona's West Coast" because it is located on the east bank of the Colorado River near the juncture of Arizona, California, and Nevada. Bullhead City serves as the economic hub and retail shopping center for Western Mohave County and Southeastern Clark County, Nevada. Given that Bullhead City is easily accessible by major highways and a short drive from Los Angeles, Phoenix, and Las Vegas, Bullhead City's economy relies heavily on tourism, including attracting visitors to its restaurants, shopping, and outdoor activities.

B. Manufacturer Defendants

1. Actavis/Allergan

33. Allergan PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis PLC acquired Allergan PLC in March 2015, and the combined company changed its name to Allergan PLC in June 2015. Before that, Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis PLC in October 2013. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is registered to do business in the State of Arizona as a Delaware corporation with its principal place of business in New Jersey, and was formerly known as Watson Pharma, Inc. Actavis PLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these Defendants is owned by Allergan PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan

PLC exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. (Allergan PLC, Actavis PLC, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to in this Amended Complaint as "Actavis.")

34. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the U.S. and Arizona. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009.

2. Cephalon/Teva

35. Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.")—not a Defendant herein—is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. Cephalon manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the United States. Actiq has been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain." Fentora has been approved by the FDA only for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

36. Teva Pharmaceuticals USA, Inc. ("Teva") is a Delaware corporation and is a wholly owned subsidiary of Teva Ltd. in Pennsylvania. It is registered to do business in Arizona.

37. Teva and Cephalon work together closely to market and sell Cephalon products in the United States. Teva conducts all sales and marketing activities for Cephalon in the United States and has done so since October of 2011. Teva holds out Actiq and Fentora as Teva products to the public. Teva sells all former Cephalon branded products

through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that the guide was submitted by Teva, and directs physicians to contact Teva to report adverse events. All of Cephalon's promotional websites, including those for Actiq and Fentora, display the Teva logo.

38. Through interrelated operations like these, Teva and Cephalon have. operated and continue to operate in the United States, including in Bullhead City. Teva and Cephalon have engaged in consensual commercial dealings in Bullhead City, and have purposefully availed themselves of the advantages of conducting business with and within Bullhead City. As alleged herein, Teva USA and Cephalon are collectively referred to as "Teva."

3. Endo

39. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals, Inc. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to as "Endo").

40. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and Arizona. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and Arizona, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

4. Janssen

41. Janssen Pharmaceuticals, Inc. (formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica, Inc.) is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson ("J&J"), a New Jersey corporation with its principal place of business

in New Brunswick, New Jersey. These entities, which are collectively referred to herein as "Janssen," acted in concert with one another—as agents and/or principals of one another—in connection with the conduct described herein. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. The Janssen and J&J parties are collectively referred to as "Janssen."

42. Janssen manufactures, promotes, sells, and distributes drugs in the U.S. and Arizona, including the opioid Duragesic. Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER, which also generated substantial sales revenue for the company, accounting for $172 million in sales in 2014 alone.

5. Johnson & Johnson

43. J&J imposes a code of conduct on Janssen as a pharmaceutical subsidiary of J&J. The "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "pharmaceutical Companies of Johnson and Johnson" and as one of the "Johnson & Johnson Pharmaceutical Affiliates." It governs how "[a]ll employees of Johnson & Johnson Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise Johnson & Johnson Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, sales associates must certify that they have "read, understood and will abide by" the code. Thus, the code governs all forms of marketing at issue in this case.

44. In addition, J&J made payments to front groups, discussed herein, who perpetuated and disseminated Defendants' misleading marketing messages regarding the risks and benefits of opioids.[16]

[16] U.S. Senate Homeland Security & Governmental Affairs Committee ("HSGAC"), Ranking Member's Office, Minority Staff Report No. 2, *Fueling an Epidemic: Exposing*

6. Purdue

45. On September 15, 2019 and September 16, 2019, Purdue Pharma L.P. and 23 affiliated debtors (collectively, the "Debtors") each filed a voluntary petition for relief under Chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the Southern District of New York. Bullhead City named Purdue and the individual Sackler defendants as parties in this case prior to their seeking and receiving protection in the Bankruptcy Court. Therefore, the discussion of Purdue and the Sacklers' contribution to the current crisis is for expository purposes only. Bullhead City is pursuing its claims against Purdue (and the Sacklers) in the bankruptcy proceedings.

46. Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware. Purdue Pharma Inc. is a New York corporation with its principal place of business in Stamford, Connecticut, and the Purdue Frederick Company is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue").

47. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER,[17] and Targiniq ER in the U.S. and Arizona. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

7. McKinsey & Co.

48. RICO Marketing unnamed co-conspirator McKinsey and Company, Inc. ("McKinsey") is a privately owned entity headquartered in New York, New York.

---

the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups, p. 4, n. 23 (2018) ("Payments from Janssen include payments from Johnson & Johnson Health Care Systems, Inc."), https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf

49. McKinsey is one of the world's largest consulting companies. Its partners work worldwide for corporations and governments across diverse industries. Its influence is vast because of its best-in-class reputation. McKinsey prides itself on the notion that it can take whatever a company or government is doing and make them do it better.

50. As alleged herein, McKinsey advised Defendants at every link in the opioid value chain, starting with their manufacture, to their distribution throughout the United States, and, finally, to their sale to consumers."

51. McKinsey's work for Defendants was an essential part of sparking and exacerbating the opioid crisis in Bullhead City. McKinsey designed many (if not all) of the aggressive promotional campaigns discussed herein, including for Purdue Pharma, Mallinckrodt, and RICO Marketing Participants Endo, Johnson & Johnson, Actavis and Teva/Cephalon.

52. In addition to designing the RICO Marketing Participants' deceptive marketing strategies, McKinsey also advised RICO Supply Chain Participants McKesson, AmerisourceBergen and Cardinal Health. In particular, McKinsey substantially assisted and encouraged the RICO Supply Chain Participants in opposing, diluting and effectively avoiding regulation under anti-diversion laws; coordinating with RICO Marketing Participants to reiterate and conceal their misrepresentations about the safety and effectiveness of prescription opioids for long-term opioid therapy; and, on information and belief, creating deceptive systems and procedures geared toward tricking insurers into paying for Defendants' opioids.

53. McKinsey's consulting work for Defendants contributed to the opioid crisis in Bullhead City..

8. The Individuals Running Purdue: Richard Sackler, Beverly Sackler, David Sackler, Ilene Sackler Lefcourt, Jonathan Sackler, Kathe Sackler, Mortimer Sackler, and Theresa Sackler

54. The Sackler family—Richard Sackler, Theresa Sackler, Kathe Sackler, Jonathan Sackler, Mortimer D.A. Sackler, Beverly Sackler, David Sackler, and Ilene Sackler

Lefcourt (collectively, "the Sacklers")—own Purdue, and they always held a majority of the seats on its Board.

55. Beverly Sackler, Jonathan Sackler, and Kathe Sackler reside in Connecticut. David Sackler, Ilene Sackler Lefcourt, and Mortimer Sackler reside in New York. Richard Sackler, resides in Florida, and Theresa Sackler resides in the United Kingdom.

9. Mallinckrodt

56. On October 12, 2020, Mallinckrodt PLC and 63 affiliated debtors (collectively, "Mallinckrodt") voluntarily initiated Chapter 11 proceedings in the U.S. Bankruptcy Court for the District of Delaware. As with the Purdue and Sackler parties, Bullhead City named Mallinckrodt as a defendant in this case prior to it seeking and receiving protection in the Bankruptcy Court. Therefore, the discussion of Mallinckrodt's contribution to the current crisis is for expository purposes only. Bullhead City is pursuing its claims against Mallinckrodt.

57. Mallinckrodt PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. Mallinckrodt PLC was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien PLC, which was fully transferred to Mallinckrodt in June of that year. Mallinckrodt began as a U.S.-based company, with the founding of Mallinckrodt & Co. in 1867; Tyco International Ltd. acquired the company in 2000. In 2008, Tyco Healthcare Group separated from Tyco International and renamed itself Covidien.

58. Mallinckrodt, LLC is a limited liability company organized and existing under the laws of the State of Delaware and licensed to do business in Arizona.

59. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, PLC.

60. Together, Mallinckrodt PLC and Mallinckrodt, LLC (collectively, "Mallinckrodt") manufacture, market, and sell drugs in the United States. As of 2012, it was the largest U.S. supplier of opioid pain medications. In particular, it is one of the largest manufacturers of oxycodone in the U.S.

61. Mallinckrodt currently manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In addition, Mallinckrodt previously developed, promoted, and sold the following branded opioid products: Magnacet, TussiCaps, and Xartemis XR.

62. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received approximately 25% of the U.S. Drug Enforcement Administration's ("DEA") entire annual quota for controlled substances that it manufactures. Mallinckrodt also estimated, based on IMS Health data for the same period, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.

63. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials, (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York, and (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.

10. The Insys Individual Defendants: John Kapoor and Michael Babich

64. Insys Therapeutics, Inc. ("Insys") is a Delaware corporation with its principal place of business in Chandler, Arizona. Insys manufactures, markets, sells and distributes nationwide several types of opioids, including Subsys—a fentanyl sublingual spray and semi-synthetic opioid antagonist—as well as Syndros, a cannabinoid medicine used in adults to treat common side-effects of opioid use, particularly for patients whose nausea and vomiting have not improved with usual anti-nausea and vomiting medicines. The FDA approved Subsys in 2012, and Syndros in 2016.

65. Subsys is indicated "for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and are tolerant to opioid

therapy for their underlying persistent cancer pain."[18] The indication also specifies that "Subsys is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain." In addition, the indication provides that "[p]atients must remain on around-the-clock opioids when taking SUBSYS." Subsys is contraindicated for, among other ailments, the "[m]anagement of acute or postoperative pain including headache/migraine and dental pain." It is available in 100 mcg, 200 mcg, 400 mcg, 600 mcg and 800 mcg dosage strengths.

66. Insys's revenue is derived almost entirely from Subsys. According to its Form 10-K for 2015, Insys reported revenues of $331 million. Of that total, $329.5 million was derived from sales of Subsys. The majority of Insys's sales of Subsys are through wholesalers, including Distributor Defendants McKesson, AmerisourceBergen and Cardinal Health. In 2015, those wholesalers respectively comprised 20%, 17% and 14% of Insys's total gross sales of Subsys.

67. John Kapoor is the founder and majority owner of Insys. In October of 2017, Defendant Kapoor was arrested in Arizona and charged with RICO conspiracy, conspiracy to commit wire fraud, and conspiracy to violate the Anti-Kickback Law, for his alleged participation in a nationwide scheme to bribe healthcare providers in various states, including Arizona, to prescribe Subsys.[19] On May 2, 2019, he was found guilty of a racketeering conspiracy and running a nation-wide bribery scheme.[20] He is a resident of

---

[18] The indication provides that "[p]atients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid daily for a week or longer."

[19] United States Department of Justice ("DOJ"), *Press Release—Founder and Owner of Pharmaceutical Company Insys Arrested and Charged with Racketeering*, U.S. Attny's Office Dist. of Mass. (Oct. 26, 2017), https://www.justice.gov/usao-ma/pr/founder-and-owner-pharmaceutical-company-insys-arrested-and-charged-racketeering

[20] Emanuel, Gabrielle, *Opioid Executive John Kapoor Found Guilty in Landmark Bribery Case* (May 2, 2019) https://www.npr.org/2019/05/02/711346081/opioid-executive-john-

Phoenix, Arizona and a current member of the Board of Directors of Insys.

68. Michael Babich is the former CEO and President of Insys. In 2017, he was also arrested in Arizona on charges of RICO conspiracy, conspiracy to commit wire fraud, and conspiracy to violate the Anti-Kickback Law. In January of 2019, Defendant Babich pleaded to these charges.[21] He is a resident of Scottsdale, Arizona.

C. Distributor Defendants

1. McKesson

69. Defendant Distributor McKesson Corporation ("McKesson") is a publicly-traded company headquartered in California, with its principal place of business at One Post Street, San Francisco, California 94104 and incorporated under the laws of Delaware. At all relevant times, McKesson was in the business of distributing substantial amounts of prescription opioids to providers and retailers. McKesson has engaged in consensual commercial dealings with Bullhead City's residents, and has purposefully availed itself of the advantages of conducting business with and within Prescott. McKesson is in the chain of distribution of prescription opioids.

2. AmerisourceBergen

70. Defendant Distributor AmerisourceBergen ("AmerisourceBergen") is a publicly traded company headquartered in Pennsylvania and incorporated under the laws of Delaware. AmerisourceBergen is in the chain of distribution of prescription opioids. At all relevant times, AmerisourceBergen was in the business of distributing substantial amounts of prescription opioids to providers and retailers. AmerisourceBergen has engaged in consensual commercial dealings with Bullhead City and its residents, and has purposefully availed itself of the advantages of conducting business with and within Bullhead City.

---

kapoor-found-guilty-in-landmark-bribery-case

[21] J. Saltzman, *Former CEO says Insys founder pushed for higher doses of opioid*, Boston Globe (Feb. 12, 2019), https://www2.bostonglobe.com/business/2019/02/12/former-ceo-says-insys-founder-pushed-for-higher-doses-opioid/aZhLcDEnayOO3dzPlFn9gN/story.html

3. Cardinal Health

71. Defendant Cardinal Health, Inc. (hereinafter "Cardinal Health") is a publicly traded company headquartered in the State of Ohio and incorporated under the laws of Ohio. Cardinal Health is in the chain of distribution of prescription opioids. At all relevant times, Distributor Cardinal Health was in the business of distributing substantial amounts of prescription opioids to providers and retailers. Cardinal Health has engaged in consensual commercial dealings with Bullhead City and its residents, and has purposefully availed itself of the advantages of conducting business with and within Bullhead City.

72. Defendants AmerisourceBergen and Cardinal Health are collectively referred to as the "Distributor Defendants." Manufacturers of opioids have transferred prescription opioids to the Distributor Defendants for years. The Distributor Defendants dominate 85 to 90 percent of all revenues from drug distribution in the United States, estimated to be at $378.4 billion in 2015. The Distributor Defendants supplied opioids to hospitals, pharmacies, doctors and other healthcare providers, which then dispensed the drugs to patients in Arizona, including in Bullhead City. The Distributor Defendants have had substantial contacts and business relationships with Bullhead City. The Distributor Defendants have purposefully availed themselves of business opportunities within Bullhead City.

D. DOE Defendants

73. Bullhead City is ignorant of the true names or capacities, whether individual, corporate or otherwise, of the Defendants sued herein under the fictitious names DOES 1 through 1000 inclusive, and they are therefore sued herein under Arizona Justice Court Rules of Civil Procedure §110. Bullhead City will amend this Amended Complaint to show their true names and capacities if and when they are ascertained. Bullhead City is informed and believes, and on such information and belief alleges, that each of the Defendants named as a DOE is responsible in some manner for the events and occurrences alleged in this Amended Complaint and is liable for the relief sought herein.

III. JURISDICTION AND VENUE

74. This Court has jurisdiction over this action. Defendants are engaging in false and misleading advertising and unlawful, unfair, and deceptive business practices in Bullhead City, and Bullhead City has the right and authority to prosecute this case.

75. Venue is proper in this Court because Defendants transact business in—and caused injury and harm to—Bullhead City and its communities. Additionally, Pharmacy Defendant Western Drug is a resident of Bullhead City, and some of the acts complained of herein also occurred in this venue. Further, Individual Defendants John Kapoor and Michael Babich reside in Arizona and both conducted and continue to conduct business throughout Arizona, including in Bullhead City. (*See* A.R.S. § 12-401, subdivs. (7), (10) and (18).)

76. This Court has subject-matter jurisdiction under 28 U.S.C. § 1331 based upon the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq.* ("RICO").

77. This Court also has diversity jurisdiction pursuant to 28 U.S.C. § 1332 because the Plaintiff has incorporated as a "citizen" of the State, the named Defendants are citizens of different states and the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

78. This Court supplemental jurisdiction over Plaintiff's state law claims because, as here, a federal district court may exercise supplemental jurisdiction over state-law claims that the court would not otherwise have subject matter jurisdiction to hear, as long as the claims are part of the same case or controversy as the claims over which the court has original jurisdiction (28 U.S.C. § 1367(a)).

79. This Court has personal jurisdiction over Defendants because they conduct business in Ohio and within Bullhead City, purposefully direct or directed their actions toward Ohio and Bullhead City, consented to be sued in Ohio by registering an agent for service of process, and/or consensually submitted to the jurisdiction of Ohio when obtaining a manufacturer or distributor license and have the requisite minimum contacts with Ohio necessary to constitutionally permit the Court to exercise jurisdiction.

80. This Court also has personal jurisdiction over all of the defendants under 18 U.S.C. § 1965(b). This Court may exercise nation-wide jurisdiction over the named Defendants where the "ends of justice" require national service and Plaintiff demonstrates national contacts. Here, the interests of justice require that Plaintiff be allowed to bring all members of the nationwide RICO enterprise before the court in a single trial. *See, e.g., Iron Workers Local Union No. 17 Insurance Fund v. Philip Morris Inc.*, 23 F. Supp. 2d 796 (1998) (citing *LaSalle National Bank v. Arroyo Office Plaza, Ltd.*, 1988 WL 23824, *3 (N.D. Ill. Mar 10, 1988); *Butcher's Union Local No. 498 v. SDC Invest., Inc.*, 788 F.2d 535, 539 (9th Cir. 1986).

81. Venue is proper in this Court pursuant to Case Management Order No. 1, subsection 6.a., *In re National Opiate Litigation*, Case No. 1:17-md-02804-DAP, wherein this Court held in relevant part, "In order to eliminate delays associated with transfer to this Court of cases filed in or removed to other federal district courts, any Plaintiff whose case would be subject to transfer to these MDL proceedings may file its case directly in this District. Direct filing shall not constitute a waiver of any party's contention that jurisdiction or venue is improper or that the action should be dismissed or transferred. Direct filing shall not impact the choice of law to be applied in the case."

82. Venue is proper in this district pursuant to 28 U.S.C. § 1391 and 18 U.S.C. § 1965 because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacted affairs and conducted activity that gave rise to the claim of relief in this District. 28 U.S.C. § 1391(b); § 1965(a).

83. Plaintiff does not bring any product liability claims or causes of action and does not seek compensatory damages for death, physical injury to person or emotional distress.

IV. FACTUAL ALLEGATIONS

A. Background on Pain Medicine

84. The practice of medicine centers on informed risk management. Prescribers must weigh the potential risks and benefits of each treatment option, as well as risk of non-

treatment. Accordingly, the safe and effective treatment of chronic pain requires that a physician be able to weigh the relative risk of prescribing opioids against both (a) the relative benefits that may be expected during the course of opioid treatment and (b) the risks and benefits of alternatives.

85. Opium has been recognized as a tool to relieve pain for millennia; so has the magnitude of its potential for abuse, addiction, and its dangers. Opioids are related to illegal drugs like opium and heroin. In fact, some types of fentanyl, a widely-distributed opioid in the United States, and have now been made illegal in China.

86. During the Civil War, opioids gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain—particularly on the battlefield—and they were popularly used in a wide variety of commercial products ranging from pain elixirs to cough suppressants and beverages. By 1900, an estimated 300,000 people were addicted to opioids in the United States. Both the number of opioid addicts and the difficulty in weaning patients from opioids made clear their highly addictive nature.

87. Due to concerns about their addictive properties, opioids have been regulated at the federal level as controlled substances by the U.S. Drug Enforcement Administration ("DEA") since 1970. The labels for scheduled opioid drugs carry black box warnings of potential addiction and "[s]erious, life-threatening, or fatal respiratory depression," as the result of an excessive dose.

88. Studies and articles from the 1970s and 1980s also made the reasons to avoid opioids clear. Scientists observed poor outcomes from long-term opioid therapy in pain management programs; opioids' mixed record in reducing pain long-term and failure to improve patients' function; greater pain complaints as most patients developed tolerance to opioids; opioid patients' diminished ability to perform basic tasks; their inability to make use of complementary treatments like physical therapy due to the side effects of opioids; and addiction. Leading authorities discouraged, and even prohibited, the use of opioid therapy for chronic pain.

89. Despite the fact that opioids are now routinely prescribed, there has never been

evidence of their safety and efficacy for long-term use. On the contrary, evidence shows that opioid drugs are not effective to treat chronic pain, and may worsen patients' health. Increasing duration of opioid use is strongly associated with an increasing prevalence of mental health condition (depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization.

90. Opioids are highly addictive. Patients using opioids for more than a few days can experience severe withdrawal symptoms if they stop taking the drugs, including: anxiety, insomnia, pain, blurry vision, rapid heartbeat, chills, panic attacks, nausea, vomiting, and tremors. Withdrawal can last so long and be so painful that it is difficult to stop taking opioids.

91. Putting patients on opioids puts them at risk. Patients who take opioids at higher doses and for longer periods face higher and higher risk of addiction and death. Relative to the general population, the risk of opioid-death is 35-times higher for patients receiving three consecutive months of opioid therapy. Each of the Defendants named in this Amended Complaint disregarded the well-known and frightening statistics regarding opioid abuse and chose to ignore them in the name of profits.

B. The RICO Opioid Marketing Participants' Impact on the Perception and Prescribing of Opioids

92. Before the Manufacturer Defendants began the marketing campaign complained of herein, the generally accepted standards of medical practice dictated that opioids should only be used short-term, for acute pain, or for patients nearing the end of life. The Manufacturer Defendants changed this perception and took advantage of addiction to make money, effectively shifting the national discussion about pain and opioids.

93. The Manufacturer Defendants' marketing campaign resulted in skyrocketing opioid prescriptions. While the shocking increase in prescriptions has been a gold mine for the Manufacturer Defendants, it has been a tragedy for Bullhead City. Bullhead City has lost citizens young and old to the opioid epidemic—too many children in Bullhead City have lost their parents and too many parents have buried their children. Too many grandparents

are raising their grandchildren.

94. Patients who survive addiction need lengthy, difficult, and expensive treatment. People who are addicted to opioids are often unable to work. The addiction of parents can force their children into foster care. Babies are born addicted to opioids, a condition known as Neonatal Abstinence Syndrome ("NAS"), because they are exposed to the drugs in the womb.


Critical Shifts in The National Discussion about Pain And Opioids

From	To
Undertreatment of Pain	Opioid Epidemic
Abuse	Addiction
Criminal	Victim
FDA	CDC
Benefits Outweigh Risks	Lack of Long-Term Evidence
ADFs as Part of Solution	ADF Value Unproven

PURDUE CONFIDENTIAL | 18

2016 Mid-Year Board Update

C. The RICO Marketing Participants Engaged in a Deceptive Marketing Scheme to Increase Profits

95. To profit from their dangerous drugs, the RICO Marketing Participants engaged in a deadly and illegal campaign to deceive doctors and patients. First, the RICO Marketing Participants deceived Bullhead City doctors and patients to get more people on their dangerous drugs. Second, the RICO Marketing Participants misled them to take higher and more dangerous doses. Third, the RICO Marketing Participants deceived them to stay on their drugs for longer and more harmful periods of time.

96. The RICO Marketing Participants targeted vulnerable people who could be

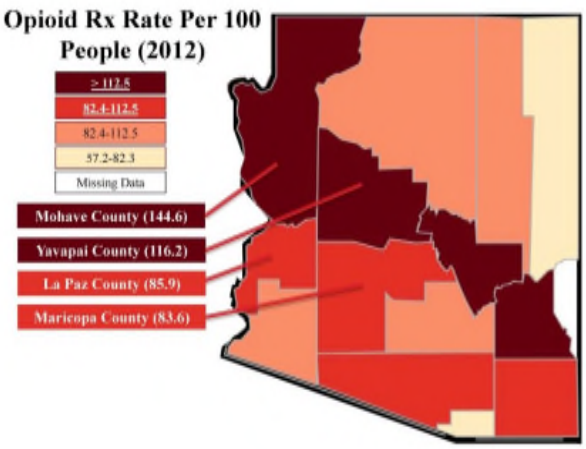
introduced to opioids, including elderly patients and people who had never taken opioids before. The RICO Marketing Participants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guidelines observed that existing evidence showed that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guidelines therefore concluded that there are "special risks of long-term opioid use for elderly patients" and recommended that doctors use "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients.

97. All the while, the RICO Marketing Participants peddled falsehoods to keep patients away from safer alternatives. Even when the RICO Marketing Participants knew people in Bullhead City were addicted and dying, the RICO Marketing Participants treated doctors and patients as "targets" to sell more drugs.

98. Each part of the scheme earned the RICO Marketing Participants more money from opioid sales and caused more addiction and death in Bullhead City. And each Defendant participated in and profited from the scheme in Bullhead City, as set forth below.

D. The RICO Opioid Marketing Participants Deceived Doctors and Patients to Get More People on Dangerous Drugs, at Higher Doses, for Longer Periods

99. Hundreds of Bullhead City patients died after taking the Manufacturer Defendants' drugs because Bullhead City was subject to the Manufacturer Defendants' massive deceptive sales campaign. The Manufacturer Defendants deceptively marketed their branded opioids directly to doctors and patients in Bullhead City. The Manufacturer Defendants also deployed sales representatives to spread their false and misleading statements about the risks and benefits of opioids for the treatment of chronic pain throughout Arizona and, specifically, in Bullhead City.



100. To convince doctors and patients around the country, including in Arizona, that opioids can and should be used to treat chronic pain, the RICO Marketing Participants had to convince them that long-term opioid use is both safe and beneficial. The RICO Marketing Participants deceived those doctors and patients about the risks and benefits of long-term opioid use. The RICO Marketing Participants, through Front Groups, KOLs, and advertisements, made claims that were not supported by or were contrary to the scientific evidence—most frequently, these claims downplayed the risks of addiction in order to convince patients and doctors alike that prescription opioids should be used more regularly. Even though pronouncements by and guidance from the FDA and the CDC based on that evidence confirm that their claims were false and misleading, Bullhead City is informed and believes the RICO Marketing Participants have not corrected them and continue to spread them today, including as set forth specifically below.

1. Deception About Addiction

101. The RICO Marketing Participants always knew that their opioids carry grave risks of addition and death. Instead of being honest about these risks, the RICO Marketing Participants obscured them, including by falsely stating and implying that "appropriate patients" won't get addicted. To convince doctors and patients that opioids are safe, the RICO Marketing Participants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC.

102. First, the RICO Marketing Participants falsely claimed that the risk of addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some illustrative examples of these false and misleading claims that were made by, are continuing to be made by, and/or have not been corrected by the RICO Marketing Participants after May 21, 2011 are described below:

a. Actavis's predecessor caused a patient education brochure to be distributed in 2007 that claimed opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond.

b. Purdue and Teva sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft.

c. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

d. Endo and Teva distributed a pamphlet with the Endo logo entitled Living with Someone with Chronic Pain, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website www.opana.com.

e. Janssen/J&J reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

f. Janssen ran a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* – which claims that less than 1% of children prescribed

opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction[]."

h. Detailers for Purdue, Endo, Teva and Janssen in Arizona have minimized or omitted and continue to minimize or omit any discussion with doctors or their medical staff in Arizona, including Bullhead City, about the risk of addiction; misrepresented that abuse-deterrent formulations "cannot be crushed," effectively downplaying the potential that these opioids would be abused; and routinely did not correct the misrepresentations noted above.

103. Moreover, Purdue, in a pamphlet for doctors, *Providing Relief, Preventing Abuse: A Reference Guide to Controlled Substance Prescribing Practices*, wrote that addiction "is not caused by drugs." Instead, Purdue assured doctors that addiction happens when the wrong patients get drugs and abuse them: "it is triggered in a susceptible individual by exposure to drugs, most commonly through abuse."[22]

104. Purdue also promoted its opioids to Bullhead City residents with marketing that was designed to obscure the risk of addiction and even the fact that Purdue was behind the campaign. Purdue created a website, *In the Face of Pain*, that promoted pain treatment by urging patients to "overcome" their "concerns about addiction." Testimonials on the website that were presented as personal stories were in fact by Purdue consultants, whom Purdue had paid tens of thousands of dollars to promote its drugs.[23]

105. Another Purdue publication, the *Resource Guide for People with Pain*, falsely assured patients and doctors that opioid medications are not addictive:

> "*Many people living with pain and even some healthcare providers believe that opioid medications are addictive. The truth is that when properly prescribed by a healthcare professional and taken as directed, these medications give relief – not a 'high'.*"[24]

---

[22] Purdue Pharma LP, *Providing Relief, Preventing Abuse* (2008), pg. 12; *see also* K. Nelson, *Purdue Pharma lawsuit: Terms you need to know to understand OxyContin blitz*, Knox News (July 13, 2018), https://www.knoxnews.com/story/news/health/2018/07/13/purdue-pharma-lawsuit-terms-know-understand-oxycontin-blitz/779173002/

[23] Purdue Pharma LP, *In the Face of Pain* (Oct. 24, 2011).

[24] Purdue Pharma LP, *Resource Guide for People with Pain*, p. 8 (2009).

106. Purdue falsely denied the risk of addiction, falsely implied that addiction requires patients to get "high," and falsely promised that patients would not get addicted if they took opioids as prescribed.

107. Purdue funded and distributed many more publications that were similarly misleading. One such publication misleadingly claimed: "Long experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications."[25]

108. *Responsible Opioid Prescribing* told doctors that only a "small minority of people seeking treatment may not be reliable or trustworthy" and not suitable for addictive opioid drugs.[26]

109. Similarly, while Janssen/J&J repeatedly disclaimed responsibility for its part in causing the opioid crisis, insisting that "[e]verything that we have done with our products when we've promoted opioid products . . . was appropriate and responsible," internal memoranda and communications between high-level executives at Janssen show the company funded and pushed bogus research to lend false credibility to a series of dangerous fictions, claiming that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain," and enabling "Janssen's representatives [to] promote[] Nucynta and Nucynta ER as safer, milder, and less addictive than competitor opioids like OxyContin."[27]

110. In 2017, Mallinckrodt agreed to settle for $35 million the Department of Justice's allegations regarding excessive sales of oxycodone in Florida. The Department of Justice alleged that even though Mallinckrodt knew that its oxycodone was being diverted to illicit use, it nonetheless continued to incentivize and supply these suspicious sales, and it

---

[25] Purdue Pharma LP, *Exit Wounds*, p. 107 (2009).

[26] Purdue Pharma LP, *Responsible Opioid Prescribing*, p. 11 (2007).

[27] M. Aron, *deceptively marketing opioids*, NJTV News (Nov. 13, 2018), https://www.njtvonline.org/news/video/state-sues-johnson-johnson-subsidiary-for-deceptively-marketing-opioids/

failed to notify the DEA of the suspicious orders in violation of its obligations as a registrant under the Controlled Substances Act, 21 U.S.C. § 801 et seq. ("CSA").

111. Similarly, in 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay $425 million.

112. Over and over, Defendants said opioids could be given to "trusted" patients without risk of addiction. To promote their drugs, the RICO Marketing Participants pushed the myth that addiction is a character flaw, and "trustworthy" people do not get addicted to drugs.

113. These claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline approved by the FDA, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])." The Guideline points out that "[o]pioid pain medication use presents serious risks, including . . . opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."

114. The FDA further exposed the falsity of the RICO Marketing Participants' claims about the low risk of addiction when it announced changes to the labels for ER/LA opioids in 2013 and for IR opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [opioids]."

115. The New York Attorney General, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated

with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder." Endo had claimed until at least April 2012 on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the NY AG found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York. Endo has not been restricted from making these statements in Arizona yet.

2. Deception to Get Vulnerable Patients on Opioids

116. To expand the market for opioids, the RICO Marketing Participants also trained their representatives to target vulnerable populations and encourage doctors to put them on opioids, without disclosing the risks. The RICO Marketing Participants deceptively promoted opioids for elderly patients, patients who had never taken opioids, and patients with osteoarthritis—putting thousands more patients at risk.

Elderly Patients

117. The RICO Marketing Participants knew that prescribing opioids to elderly patients increase their risk of death. Elderly patients are at greater risk of dangerous interactions between drugs. They are also at a greater risk of respiratory depression—in which patients suffocate and die. But the RICO Marketing Participants saw the opportunity to earn millions of dollars by getting elderly patients on opioids because the public would pay through Medicare. For instance, Purdue's internal documents show it targeted "Patients over the age of 65 as more Medicare Part D coverage is achieved."[28]

Opioid-Naïve Patients

118. The RICO Marketing Participants also targeted patients who were not already taking opioids, described in the field as "opioid-naïve." The RICO Marketing Participants

[28] Purdue Pharma LP, *Pain Products Presentation*, p. 12 (Jan. 28, 2015).

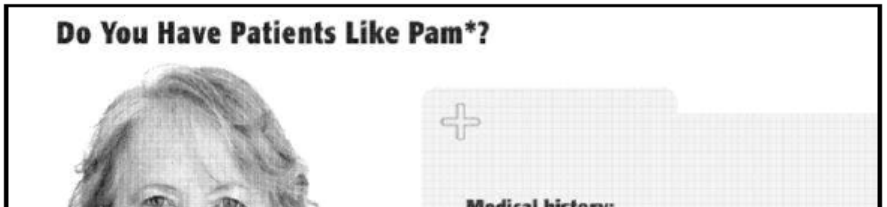
unfairly and deceptively marketed their drugs as appropriate treatments for opioid-naïve patients, without disclosing that they face even higher risks of overdose and death.

119. For instance, Purdue trained its sales reps to promote their drugs specifically for opioid-naïve patients. In training calls, Purdue managers instructed:

- *"Your opportunity here is with the naïve community, let's use the naïve trial to make the case."*
- *"You created an epiphany with the doctor today (potentially) by reviewing the opiate naïve patient profile. What made him more apt to write this for his patient, being an amiable doctor, is the fact that he would not have to talk patients out of their short-acting [opioids]."*
- *"This was an example of what a good call looks like . . . [Dr.] was particularly interested in the RM case study of Marjorie, which generated a robust discussion of opioid naïve patients . . . ."*

120. Purdue also promoted its drugs for opioid-naïve patients using the deceptive term "first line opioid." "First line" is a medical term for the preferred first step in treating a patient. Opioids are not an appropriate first line therapy.

[REMAINDER OF PAGE INTENTIONALLY BLANK.]



121. The RICO Marketing Participants also found vulnerable opioid-naïve patients by targeting prescribers with the least training in the risks of opioids. The RICO Marketing Participants determined that nurse practitioners, physician assistants, and primary care doctors were especially responsive to sales reps, so it targeted them to sell more drugs.

122. The RICO Marketing Participants knew that opioids were not appropriate to treat nonmalignant pain in non-cancer patients, including patients suffering from osteoarthritis. Opioids are not approved to treat osteoarthritis. For instance, Purdue conducted a single study on osteoarthritis for Butrans, and it failed. Purdue admitted in internal documents that its opioids "are not indicated for a specific disease" and "it is very important that you never suggest to your HCP [health care professional] that OxyContin is indicated for the treatment of a specific disease state such as Rheumatoid Arthritis or Osteoarthritis."

123. Nevertheless, to meet their business goals, the RICO Marketing Participants

trained their sales representatives to mislead doctors by promoting opioids for osteoarthritis. For instance, a Purdue marketing presentation concluded that its sales reps were "identifying appropriate patients" because osteoarthritis was specifically mentioned during at least 35% of sales visits.

124. The RICO Marketing Participants also directed their sales reps to use marketing materials that highlight patients with osteoarthritis, even though their drugs were never indicated for that disease.

3. The RICO Opioid Marketing Participants Deceived Doctors and Patients to Use Higher and Higher Doses

125. The impetus behind the RICO Marketing Participants' scheme is as simple as it is nefarious. Enticed by the exponentially greater profits that would result from increases in opioid dose mix, the RICO Marketing Participants deceived (or bribed) Bullhead City's local prescribers in order to increase the supply of prescription opioids in Plaintiff's territory and drown Plaintiff's community in a sea of highly addictive, prescription drugs.

126. The RICO Marketing Participants also falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants called this phenomenon "pseudoaddiction"—a made-up, misleading and scientifically unsubstantiated term coined by Dr. David Haddox (who went on to work for Purdue), and popularized by Dr. Russell Portenoy, a KOL for Endo, Janssen, Teva, and Purdue. Through aggressive marketing campaigns to prescribers and patients—including prescribers and patients in Bullhead City—the RICO Marketing Participants used the concept of "pseudoaddiction" as a lever to mislead prescribers and their patients into believing that certain warning signs of opioid addiction[29] were neither indicative of "true" addiction, nor cause for alarm. To the contrary, the RICO Marketing Participants repeatedly claimed that drug-seeking behavior was a manifestation of

[29] *E.g.*, demanding more opioids, engaging in manipulative behavior to obtain drugs, requesting specific drugs, hoarding drugs during periods of reduced symptoms, using drugs for unapproved purposes, etc.

undertreated pain, which should be addressed by prescribing even more opioids. Importantly, at all times relevant to this action, the RICO Marketing Participants knew the concept of pseudoaddiction was false, yet actively sought to conceal the truth from Bullhead City's physicians and patients, effectively sabotaging these prescribers' ability to protect their patients from opioid addiction and concomitant injuries. Some illustrative examples of these deceptive claims that were made by, are continuing to be made by, and/or have not been corrected by the RICO Marketing Participants are described below:

a. Purdue, Teva and Endo sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name", "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction. This publication remains for sale online.

b. Janssen sponsored, funded, and edited the Let's Talk Pain website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."

c. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."

e. Purdue sponsored a CME program entitled "Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse" in 2011. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid.

f. Detailers for Purdue have directed doctors and their medical staffs in

Arizona, including Bullhead City, to PartnersAgainstPain.com, which contained false and misleading materials describing pseudoaddiction.

g. Purdue and Teva sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which states: "Pseudo-addiction describes patient behaviors that may occur when pain is undertreated . . . Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated." (emphasis added.)

127. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

128. Even one of the RICO Marketing Participants has effectively repudiated the concept of pseudoaddiction. In finding that "[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents," the NY AG, in its 2016 settlement with Endo, reported that "Endo's Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the 'pseudoaddiction' concept" and acknowledged the difficulty in distinguishing "between addiction and 'pseudoaddiction.' "[30] Consistent with this testimony, Endo agreed not to "use the term 'pseudoaddiction' in any training or marketing" in New York.[31]

129. The RICO Marketing Participants also falsely instructed doctors and patients that addiction risk screening tools—such as patient contracts, urine drug screens, and similar strategies—would allow prescribers to reliably identify and safely prescribe opioids to patients predisposed to (or exhibiting warnings signs of) opioid addiction and misuse.

[30] In the Matter of Endo Health Solutions Inc. *et al*, Assurance No. 15-228, p. 7, ¶ 23 (NY AG, Mar. 1, 2016), https://www.ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

[31] *Id.*, p. 15, ¶ 41.e.

Indeed, the RICO Marketing Participants emphasized that these tools would be efficacious enough to essentially rule out the risks of opioid addition and misuse—even for patients receiving long-term opioid therapy. These misrepresentations were especially insidious because the RICO Marketing Participants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. The RICO Marketing Participants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Some illustrative examples of these deceptive claims that were made by, are continuing to be made by, and/or have not been corrected by the RICO Marketing Participants after March 21, 2011 are described below:

a. Endo paid for a 2007 supplement in the Journal of Family Practice written by a doctor who became a member of Endo's speakers bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

b. Purdue sponsored a November 2011 webinar, Managing Patient's Opioid Use: Balancing the Need and Risk, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

c. As recently as 2015, Purdue has represented in scientific conferences that "bad apple" patients—and not opioids—are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

d. Since at least May 21, 2011, detailers for Purdue have touted and continue to tout to doctors in Arizona, including Bullhead City, the reliability and effectiveness of screening or monitoring patients as a tool that would virtually eliminate the risks of opioid abuse and addiction.

130. Once again, the 2016 CDC Guideline confirms that these statements were false, misleading and unsupported at the time they were made by the RICO Marketing Participants. The Guideline notes that there are no studies the efficacy of the above-referenced risk mitigation strategies is not substantiated by the clinical evidence. Informed

by a systematic review of the scientific evidence while considering benefits and harms, values and preferences, and resource allocation," the CDC Guideline found that instruments for predicting risk for opioid overdose, addiction, abuse or misuse "were extremely inconsistent," as many studies purporting to endorse the accuracy of these instruments "had serious methodological shortcomings."[32] The CDC Guideline further found that "[n]o study evaluated the effectiveness of . . . opioid management plans, patient education, urine drug testing, use of PDMP data, use of monitoring instruments, more frequent monitoring intervals, pill counts, or use of abuse-deterrent formulations," for purposes of "improving outcomes related to overdose, addiction, abuse, or misuse."[33] As a result, the Guideline recognizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that prescribers "*should not overestimate* the ability of these tools to rule out risks from long-term opioid therapy."[34]

4. The RICO Opioid Marketing Participants Peddled Falsehoods to Keep Patients Away from Safer Alternatives

A. Deception about Lower-Dose Opioids

131. The RICO Marketing Participants deceptively claimed that its opioids provided more effective pain relief than traditional immediate-release opioids (sometimes called "IROs"). For instance, Purdue's records show that the sales reps repeatedly claimed that OxyContin's "steady state is better than peak and trough w/ [IROs]." Purdue claimed that OxyContin provides a "full tank of gas," but immediate-release opioids require "stopping at each exit to refuel." Purdue bolstered these misrepresentations with marketing materials that misrepresented data to indicate that Purdue drugs provided more consistent

---

[32] *See generally* Deborah Dowell, MD, *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, CDC.gov (Mar. 18, 2016) (the "CDC Guideline"), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htmhttps://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

[33] *Id.*

[34] *Id.* (emphasis added).

pain relief than more frequently dosed, lower-dose opioids.

B. Deception about Quality of Life

132. The RICO Marketing Participants also steered patients away from safer alternatives with the false claim that its opioids improve patients' "quality of life." For instance, Purdue's internal documents admit that "Purdue has no clinical studies or other substantial evidence demonstrating that a Purdue Product will improve the quality of a person's life." Nevertheless, Purdue sales reps repeatedly claimed that its opioids improve quality of life. Purdue also devised and funded third-party publications to say that opioids give patients the "quality of life we deserve."

C. Deception about Risk of Abuse

133. In addition to visiting prescribers and pharmacists hundreds of thousands of times, the RICO Marketing Participants distributed thousands of copies of its deceptive publications, including *Providing Relief*, *Preventing Abuse*; *Resource Guide for People with Pain*; *Exit Wounds*; *Opioid Prescribing: Clinical Tools and Risk Management Strategies*; *Responsible Opioid Prescribing*; and *Clinical Issues in Opioid Prescribing. Purdue's In The Face of Pain*.

5. The RICO Opioid Marketing Participants Downplayed Opioids Withdrawal

134. To downplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, the RICO Marketing Participants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and failed to disclose the increased difficulty of stopping opioids after long-term use. For example, a 2011 non-credit educational program sponsored by Endo, entitled "Persistent Pain in the Older Adult," claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might

occur. This publication was available on APF's website until the organization dissolved in May 2012. And detailers for Janssen have told and continue to tell doctors in Arizona, including Bullhead City, that their patients would not experience withdrawal if they stopped using opioids.

135. The RICO Marketing Participants deceptively minimized the significant symptoms of opioid withdrawal—which, as explained in the 2016 CDC Guideline, include drug craving, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking or exacerbating of anxiety, depression, and addiction—and grossly understated the difficulty of tapering, particularly after long-term opioid use. The 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be "limit[ed]" to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms," because "physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days." The Guideline further states that "tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence" and highlights the difficulties, including the need to carefully identify "a taper slow enough to minimize symptoms and signs of opioid withdrawal" and to "pause[] and restart[]" tapers depending on the patient's response. The CDC also acknowledges the lack of any "high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued."

136. Some prescribers and many residents in Bullhead City relied on the truth of the Manufacturers Defendants' representations about both the benefits of opioid analgesics and the risks of opioid addiction. Because each of the RICO Marketing Participants willfully concealed the truth about their products and knew their representations were false at the time they were made, Bullhead City's citizens are forced to pay the price for Defendants' misconduct.

6. The RICO Opioid Marketing Participants Hid the Greater Risks to Patients at Higher Dosages of Opioids

137. The RICO Marketing Participants were in the best position to know, and in fact did know, that—relative to the general population—the risk of opioid-related death increases exponentially after a patient takes opioids for several consecutive months.

138. Specifically, the RICO Marketing Participants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to the RICO Marketing Participants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. Some illustrative examples of these deceptive claims that were made by, are continuing to be made by, and/or have not been corrected by the RICO Marketing Participants after May 21, 2011 are described below:

a. Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond.

b. Purdue and Teva sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain.[35]

[35] The Manufacturer Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of a competing class of analgesics: over-the-counter nonsteroidal anti-inflammatories (or NSAIDs). The Manufacturer Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids. (*See, e.g.*, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) (describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids); *Finding Relief: Pain Management for Older Adults* (Janssen) (NSAIDs caused kidney or liver

c. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain." The website was still accessible online after May 21, 2011.

d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was still available after May 21, 2011 on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."

e. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.

f. Through March 2015, Purdue's In the Face of Pain website promoted the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online.

h. Purdue sponsored a CME entitled Overview of Management Options that is still available for CME credit. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence challenging the correlation between opioid dosage and overdose.

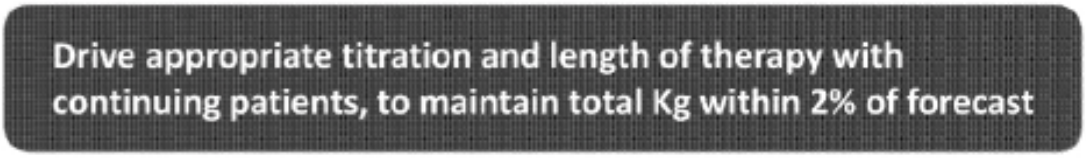
j. Since at least May 21, 2011, Purdue's detailers have told doctors in Arizona, including in Bullhead City, that they should increase the dose of OxyContin, rather than the frequency of use, to address early failure.

139. Through a series of internal strategy presentations and other communications

---

damage and increased risk of heart attack and stroke, versus opioids, which cause temporary "upset stomach or sleepiness" and constipation).)

with its sales force and prescriber-accomplices, Purdue aimed to "drive" patients toward higher doses of opioids for longer periods by dramatically increasing the supply. Purdue also sought to increase consumer demand for opioids, namely by offering discounts to patients on their first prescriptions. These discounts ultimately proved to be one of Purdue's most powerful tactics to keep patients on opioids longer, as Purdue's return on investment from these discounts was a staggering 4.28—*i.e.*, every $1,000,000 Purdue gave away in first-time patient discounts came back to Purdue as $4,280,000 in revenue.



Purdue internal strategy presentation from 2012

140. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC also states that "there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages." That is why the CDC advises doctors to "avoid increasing dosages" above 90 morphine milligram equivalents per day.

141. The 2016 CDC Guidelines reinforce earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality." In fact, a recent study found that 92% of persons who died from an opioid-related overdose were initially prescribed opioids for chronic pain.

142. Finally, the RICO Marketing Participants' deceptive marketing of the so-

called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can prevent and curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.

143. These abuse deterrent formulations ("AD opioids") are harder to crush, chew, or grind; become gelatinous when combined with a liquid, making them harder to inject; or contain a counteragent such as naloxone that is activated if the tablets are tampered. Despite this, AD opioids are "not impossible" to abuse.[36] They can be defeated—often quickly and easily—by those determined to do so. Moreover, they do not stop oral intake, the most common avenue for opioid misuse and abuse, and do not reduce the rate of misuse and abuse by patients who become addicted after using opioids long-term as prescribed or who escalate their use by taking more pills or higher doses.

144. Because of these significant limitations on AD opioids and because of the heightened risk for misconceptions and for the false belief that AD opioids can be prescribed safely, the FDA has cautioned that any communications from the sponsor companies regarding AD properties must be truthful and not misleading (based on a product's labeling), and supported by sound science taking into consideration the totality of the data for the particular drug. Claims for AD opioid products that are false, misleading, and/or insufficiently proven do not serve the public health.[37]

145. Notwithstanding this admonition, the RICO Marketing Participants have made and continue to make misleading claims about the ability of their AD opioids to prevent or reduce abuse and addiction, as well as the safety of these formulations.

146. For example, Endo has marketed Opana ER as tamper- or crush-resistant and less prone to misuse and abuse since at least May 21, 2011 even though: (1) the FDA rejected

---

[36] *See* U.S. Food and Drug Administration ("FDA"). *Abuse-Deterrent Opioids—Evaluation and Labeling: Guidance for Industry*, p. 23 (Apr. 2015), https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm334743.pdf

[37] *Ibid.*

Endo's petition to approve Opana ER as abuse-deterrent in 2012; (2) the FDA warned in a 2013 letter that there was no evidence that Opana ER "would provide a reduction in oral, intranasal or intravenous abuse"; and (3) Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. Endo's advertisements for the 2012 reformulation of Opana ER falsely claimed that Opana ER could not be crushed, creating the impression that the drug was more difficult to abuse. Indeed, since 2012 detailers for Endo have misinformed prescribers in Arizona and Bullhead City that Opana ER cannot be crushed. For example, prescribers have reported receiving tamper- and crush-resistant messages regarding Opana ER as well as demonstrations of its abuse-deterrent properties.

147. In the 2016 settlement with the NY AG, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The NY AG found those statements false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy benefit managers.

148. Because Opana ER could be "readily prepared for injection" and was linked to outbreaks of HIV and a serious blood disease, in May 2017, an FDA advisory committee recommended that Opana ER be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017 and requested that Endo withdraw Opana ER from the market.[38]

149. Likewise, Purdue has engaged and continues to engage in deceptive marketing of its AD opioids—*i.e.*, reformulated OxyContin and Hysingla—since at least May 21, 2011. Before April 2013, Purdue did not market its opioids based on their abuse deterrent properties. However, numerous Arizona prescribers report that detailers from Purdue have

[38] FDA News Release, *FDA requests removal of Opana ER for risks related to abuse* (June 8, 2017), https://www.fda.gov/news-events/press-announcements/fda-requests-removal-opana-er-risks-related-abuse

regularly used the so-called abuse deterrent properties of Purdue's opioid products as a primary selling point to differentiate those products from their competitors. Specifically, these detailers: (1) claim that Purdue's AD opioids prevent tampering and cannot be crushed or snorted; (2) claim that Purdue's AD opioids prevent or reduce opioid misuse, abuse, and diversion, are less likely to yield a euphoric high, and are disfavored by opioid abusers; (3) Purdue's AD opioids are "safer" than other opioids; and (4) fail to disclose that Purdue's AD opioids do not impact oral abuse or misuse and that its abuse deterrent properties can be defeated.

150. These statements and omissions by Purdue are false and misleading and conflict with or are inconsistent with the FDA-approved label for Purdue's AD opioids—which indicates that abusers do seek them because of their high likability when snorted, that their abuse deterrent properties can be defeated, and that they can be abused orally notwithstanding their abuse deterrent properties and which does not indicate that AD opioids prevent or reduce abuse, misuse, or diversion.

151. To the contrary, testimony in litigation against Purdue and other evidence indicates that Purdue knew and should have known that "reformulated OxyContin is not better at tamper resistance than the original OxyContin" and is still regularly tampered with and abused. Websites and message boards used by drug abusers, such as bluelight.org and reddit, also report a variety of ways to tamper with OxyContin and Hysingla, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which the tablet has been dissolved. Even Purdue's own website describes a study it conducted that found continued abuse of OxyContin with so-called abuse deterrent properties. Finally, there are no studies indicating that Purdue's AD opioids are safer than any other opioid products.

152. A 2015 study also shows that many opioid addicts are abusing Purdue's AD opioids through oral intake or by defeating the abuse deterrent mechanism. Indeed, one-third of the patients in the study defeated the abuse deterrent mechanism and were able to continue inhaling or injecting the drug. And to the extent that the abuse of Purdue's AD

opioids was reduced, those addicts simply shifted to other drugs such as heroin.[39] Despite this, J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's AD opioids are being abused in large numbers.

153. Similarly, the 2016 CDC Guideline notes that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," warning that these technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes."[40] Moreover, the 2016 CDC Guideline expressly states "that continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[41] Tom Frieden, the Director of the CDC, has further reported that his staff could not find "any evidence showing the updated opioids [ADFs] actually reduce rates of addiction, overdoses, or death."[42] The 2016 CDC Guideline further

154. These false and misleading claims about the abuse deterrent properties of their opioids are especially troubling. First, the RICO Marketing Participants are using these claims in a spurious attempt to rehabilitate their image as responsible opioid manufacturers. Indeed, Purdue has conveyed that its sale of AD opioids is "atonement" for its earlier sins even though its true motive was to preserve the profits it would have lost when its patent for OxyContin expired. Purdue introduced its first AD opioid days before that patent would have expired and petitioned the FDA to withdraw its non-AD opioid as unsafe and; thereby,

---

[39] Cicero, Theodore J., and Matthew S. Ellis, *Abuse-deterrent formulations and the prescription opioid abuse epidemic in the United States: lessons learned from Oxycontin*, 72.5 JAMA Psychiatry, 424-30 (2015).

[40] *See generally* Deborah Dowell, MD, *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, CDC.gov (Mar. 18, 2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htmhttps://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

[41] *Id.*

[42] Perrone, *Drugmakers push profitable, but unproven, opioid solution*, The Associated Press (Dec. 15, 2016), https://publicintegrity.org/state-politics/drugmakers-push-profitable-but-unproven-opioid-solution.

preventing generic competition. Second, these claims are falsely targeting doctors' concerns about the toll caused by the explosion in opioid prescriptions and use and encouraging doctors to prescribe AD opioids under the mistaken belief that these opioids are safer, even though they are not. Third, these claims are causing doctors to prescribe more AD opioids—which are far more expensive than other opioid products even though they provide little or no additional benefit.

155. These numerous, longstanding misrepresentations of the risks of long-term opioid use spread by Defendants successfully convinced doctors and patients to discount those risks.

7. The RICO Opioid Marketing Participants Grossly Overstated the Benefits of Chronic Opioid Therapy

156. To convince doctors and patients that opioids should be used to treat chronic pain, the RICO Marketing Participants also had to persuade them that there was a significant upside to long-term opioid use. But as the 2016 CDC Guideline makes clear, there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks." Despite this, the RICO Marketing Participants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have the RICO Marketing Participants failed to correct these false and misleading claims, they continue to make them today.

157. For example, the RICO Marketing Participants falsely claimed that long-term opioid use improved patients' function and quality of life. Some illustrative examples of

these deceptive claims that were made by, are continuing to be made by, and/or have not been corrected by the RICO Marketing Participants after May 21, 2011 are described below:

a. Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.

b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.

c. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"

d. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.

e. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Endo, Teva and Purdue, taught that relief of pain by opioids, by itself, improved patients' function.

f. Purdue and Teva sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve."

g. Endo's NIPC website painknowledge.com claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

h. Endo was the sole sponsor, through NIPC, of a series of non-credit educational programs titled Persistent Pain in the Older Patient, which

claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

i. Janssen sponsored, funded, and edited a website, Let's Talk Pain, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function."

j. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients."

k. In a 2015 video on Forbes.com discussing the introduction of Hysingla ER, Purdue's Vice President of Health Policy, J. David Haddox, talked about the importance of opioids, including Purdue's opioids, to chronic pain patients' "quality of life," and complained that CDC statistics do not take into account that patients could be driven to suicide without pain relief.

l. Since at least May 21, 2011, Purdue's, Endo's, Teva's and Janssen's sales representatives have conveyed and continue to convey to prescribers in Arizona, including in Bullhead City, the message that opioids will improve patient function.

158. These claims find no support in the scientific literature. The FDA and other federal agencies have made this clear for years. Most recently, the 2016 CDC Guideline approved by the FDA concluded that "there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely." The CDC reinforced this conclusion throughout its 2016 Guideline:

- *"No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . ."*

- *"Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy."*

- *"[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which*

opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."

159. The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations." As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

160. The 2016 CDC Guideline was not the first time a federal agency repudiated Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis, in response to its advertising described above, that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience … results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life." And in 2008, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

161. The RICO Marketing Participants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. For example, the RICO Marketing Participants, before and after May 21, 2011, have overstated the number of deaths from NSAIDS and have prominently featured the risks of NSAIDS, while minimizing or failing to mention the serious risks of opioids. Once again, these misrepresentations by the RICO Marketing Participants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the

first-line treatment for chronic pain, particularly arthritis and lower back pain.

8. The RICO Opioid Marketing Participants Also Engaged in Other Unlawful and Unfair Misconduct

162. Since at least 2010, Purdue's sales representatives have pressed doctors to prescribe its opioids in order to be rewarded with talks paid by Purdue.

163. Although the U.S. Drug Enforcement Administration ("DEA") has repeatedly informed Purdue about its legal "obligation to design and operate a system to disclose . . . suspicious orders of controlled substances" and to inform the DEA "of suspicious orders when discovered," Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs after 2010, despite knowing about it for years.

164. For over a decade, Purdue has been able to track the distribution and prescribing of its opioids down to the retail and prescriber levels. Through its extensive network of sales representatives, Purdue had and continues to have knowledge of the prescribing practices of thousands of doctors in Arizona and could identify Arizona doctors who displayed red flags. Using this information, Purdue has maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin—the same OxyContin that Purdue had promoted as less addictive—in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused.

165. In an interview with the Los Angeles Times, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action—even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite Purdue's knowledge of illegal prescribing, Purdue did not report until after law enforcement shut down clinics that overprescribed OxyContin tablets and that Purdue's district manager described internally as "an organized drug ring." In doing so, Purdue protected its own profits at the expense of public health and

safety.

166. This misconduct by Purdue is ongoing. In 2016, the NY AG found that, between January 1, 2008 and March 7, 2015, Purdue's sales representatives, at various times, failed to timely report suspicious prescribing and continued to detail those prescribers even after they were placed on a "no-call" list.

167. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health Services, said in a Los Angeles Times article, "Any drug company that has information about physicians potentially engaged in illegal prescribing or prescribing that is endangering people's lives has a responsibility to report it." The NY AG's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. Yet, on information and belief, Purdue continues to profit from the prescriptions of such prolific prescribers in Arizona, including in Bullhead City.

168. Like Purdue, Defendant Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the NY AG found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list. The NY AG also found that, in certain cases where Endo's sales representatives detailed prescribers who were convicted of illegal opioid prescribing after May 21, 2011, those representatives could have recognized potential signs of diversion and reported those prescribers but failed to do so.

E. Although the RICO Opioid Marketing Participants Knew Their Opioid Marketing Was False and Misleading, They Fraudulently Concealed Their Misconduct

169. The RICO Marketing Participants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and

misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned the RICO Marketing Participants of this, and Purdue entered into settlements in the hundreds of millions of dollars to address similar misconduct that occurred before 2008. The RICO Marketing Participants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of the RICO Marketing Participants' misrepresentations, and Endo and Purdue have recently entered agreements prohibiting them from making some of the same misrepresentations described in this Amended Complaint in New York.

170. Moreover, at all times relevant to this Complaint, the RICO Marketing Participants concealed their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the RICO Marketing Participants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. The RICO Marketing Participants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of the RICO Marketing Participants' false and misleading statements about the risks and benefits of long-term opioid use for chronic pain.

171. The RICO Marketing Participants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. The RICO Marketing Participants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, painknowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other RICO Marketing Participants, such as Purdue and Janssen, ran similar

websites that masked their own direct role.

172. Finally, the RICO Marketing Participants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. The RICO Marketing Participants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for the RICO Marketing Participants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by Plaintiff.

173. Thus, the RICO Marketing Participants successfully concealed from the medical community, patients, and health care payors facts sufficient to arouse suspicion of the claims that Plaintiff now asserts. Plaintiff did not know of the existence or scope of the RICO Marketing Participants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

F. The RICO Opioid Marketing Participants Funneled Misrepresentations Through Sales Representatives, Advertisements, and Third-Parties

174. Despite knowing their opioids were highly addictive and prone to result in dependence and abuse, the RICO Marketing Participants, in order to increase sales, undertook a massive marketing campaign premised on misleading prescribers and the public about the risks and benefits of chronic opioid therapy. The essence of this scheme was to spread false and incomplete information that grossly overstated the benefits of opioids for the long-term treatment of chronic pain, while minimizing the significant risks of addiction and death.

175. Indeed, many Bullhead City residents died after taking Defendants' drugs because Bullhead City was subject to the RICO Marketing Participants' relentless, methodically untruthful advertising campaign. In furtherance of this scheme, each of the RICO Marketing Participants fraudulently increased their opioid sales in Bullhead City in the following ways: **1)** dispatching thousands of sales representatives to visit doctors and other prescribers in and around Bullhead City, to convince them to change their prescribing

practices; **2)** spending millions of dollars on both branded and unbranded advertising, which overstated the benefits of opioid use and minimized the risks of addiction and overdose when opioids were used to treat chronic pain; **3)** paying Key Opinion Leader physicians to corroborate the RICO Marketing Participants' misrepresentations in an effort to convince insurers to add opioids to their formularies, and creating and sponsoring prescriber training materials that repeatedly and systematically misrepresented the safety and efficacy of opioids for treating long-term, chronic pain; and **4)** entering into arrangements with seemingly unbiased and independent patient and professional organizations—which, in fact, were controlled and/or funded by the RICO Marketing Participants—to falsely tout the benefits of opioids and dishonestly minimize the risk of opioid overdose and addiction, effectively allowing the RICO Marketing Participants to act under the guise of independent third parties.

1. Defendants' Sales Representatives Deceptively Promoted Opioids in Face-to-Face Meetings with Prescribers

176. These representatives were the Manufacturer Defendants' most powerful tools of deception. To further the Opioid Marketing Enterprise and achieve the RICO Marketing Participants' common goal of illegally increasing opioid sales, Manufacturer Defendants dispatched legions of sales representatives to promote opioids to Arizona prescribers face to face, including in Bullhead City. During sales visits, these representatives made false and misleading claims directly to the professionals who care for Bullhead City residents.The Manufacturer Defendants assigned representatives to Bullhead City and gave them lists of Bullhead City prescribers to visit. The 'scripts' used by these representatives were approved and closely monitored by the Manufacturer Defendants, to ensure consistency with the overarching aims of the Opioid Marketing Enterprise.

177. The RICO Marketing Participants, and each of them, devoted and continue to devote massive resources to direct sales contacts ("detailing") with doctors. In 2014 alone, the Manufacturer Defendants spent $168 million on detailing branded opioids to doctors. This amount is twice as much as opioid manufacturers spent on detailing in 2000, and

includes $108 million spent by Purdue, $34 million by Janssen, $10 million by Endo, and $2 million by Actavis.

178. Each of these visits cost the Manufacturer Defendants money. But the Manufacturer Defendants, in connection with the Opioid Marketing Enterprise, made this money back many times over, because they convinced doctors to prescribe their addictive drugs. The Manufacturer Defendants rewarded high prescribing doctors with meals, money, and gifts. The Manufacturer Defendants' sales representatives who generated the most prescriptions won bonuses and prizes. These representatives have spread and continue to spread misinformation regarding the risks and benefits of opioids to hundreds of thousands of doctors, and other healthcare providers, including those in Bullhead City.

179. The Manufacturer Defendants' representatives have been reprimanded for their deceptive promotions. A July 2010 "Dear Doctor" letter mandated by the FDA required Actavis to acknowledge to the doctors to whom it marketed its drugs that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."

2. RICO Marketing Participants' Spent Millions on Deceptive Advertising for Their Branded and Unbranded Opioids

180. Each of the RICO Marketing Participants expended millions of dollars on both branded and unbranded opioid advertisements, which falsely touted the purported risks and benefits of their drugs for treating long-term chronic pain. To achieve the goals of the Opioid Marketing Enterprise, the Manufacturer Defendants spent more than $14 million on medical journal advertising of opioids in 2011—nearly triple what they spent in 2001. This amount included $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.

181. Likewise, a number of the Manufacturer Defendants' ***branded ads*** deceptively portrayed the benefits of opioids for chronic pain. For example, since at least May 21, 2011,

Endo has distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Purdue also ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively. Endo and Purdue agreed in late 2015 and 2016 to halt these misleading representations in New York, but they may continue to disseminate them in Arizona.

182. Similarly, despite Subsys' limited indication and the potent danger associated with fentanyl, Insys falsely and misleadingly marketed Subsys to doctors as an effective treatment for back pain, neck pain and other off-label pain conditions. As of June 2012, Insys defined BTP in cancer patients to include mild pain: a "flare of mild-to-severe pain in patients with otherwise stable persistent pain," based on a misleading citation to a paper written by Dr. Russell Portenoy.[43] Insys trained and instructed its sales representatives to use the false definition of breakthrough pain and specifically to use a core visual aid, including the improper definition, whenever they detailed Subsys to a healthcare provider or provider's office.

183. According to a 2014 article in *The New York Times*, only 1% of prescriptions for Subsys were written by oncologists. Approximately half the prescriptions were written by pain specialists, with others, including dentists and podiatrists, writing prescriptions as well.[44]

---

[43] Portenoy's paper, which was featured in the 1990 issue of Pain, actually defined breakthrough pain as "a transitory increase in pain to greater than moderate intensity—i.e., to an intensity of 'severe' or 'excruciating') . . . on a baseline pain of moderate intensity or less." Russell K. Portenoy & Neil A. Hagen, *Breakthrough pain: Definition, prevalence and characteristics*, 41(3) Pain 273-81 (July 1990).

[44] Katie Thomas, *Doubts Raised About Off-Label Use of Subsys, a Strong Painkiller*, N.Y. TIMES (May 13, 2014), https://www.nytimes.com/2014/05/14/ business/doubts-raised-aboutoff-label-use-of-subsys-a-strong-painkiller.html.

184. On September 6, 2017, Senator Claire McCaskill's report, "Fueling an Epidemic: Insys Therapeutics and the System Manipulation of Prior Authorization" was published. The report found that Insys manipulated the prior authorization process by, for instance, misleading pharmacy benefit managers about the role of Insys in the prior authorization process and the presence of breakthrough cancer pain in potential Subsys patients.[45]

185. On September 12, 2017, Senator McCaskill convened a Roundtable Discussion on Opioid Marketing. During the hearing, Senator McCaskill stated:

> "The opioid epidemic is the direct result of a calculated marketing and sales strategy developed in the 90's, which delivered three simple messages to physicians. First, that chronic pain was severely undertreated in the United States. Second, that opioids were the best tool to address that pain. And third, that opioids could treat pain without risk of serious addiction. As it turns out these messages were exaggerations at best and outright lies at worst.
>
> * * *
>
> "Our national opioid epidemic is complex, but one explanation for this crisis is simple, pure greed."[46]

186. Less than two years later, Insys' former chief executive officer—Individual and RICO Marketing Defendant Michael Babich—pleaded guilty to participating in a nationwide scheme to bribe doctors in exchange for prescribing Subsys.[47] Four months thereafter, Insys' founder and majority shareholder—Individual and RICO Defendant John

---

[45] Prior authorization (PA) is any process by which physicians and other health care providers must obtain advance approval from a health plan before a specific procedure, service, device, supply or medication is delivered to the patient to qualify for payment coverage. (American Medical Association, *Prior authorization: The current landscape*, p. 1 (2015), https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/premium/psa/prior-authorization-toolkit_0.pdf

[46] *See*, *LIVESTREAM: Insys Opioid Sales and Marketing Practices Roundtable*, September 12, 2017, at 31:03-31:37, https://www.youtube.com/watch?v=k9mrQa8_vAo (last accessed Mar. 17, 2019).

[47] Nate Raymon, *Former Insys CEO pleads guilty to opioid kickback scheme*, REUTERS (Jan. 9, 2019), https://www.reuters.com/article/us-insys-opioids/former-insys-ceo-pleads-guilty-to-opioid-kickback-scheme-idUSKCN1P312L.

Kapoor—was found guilty for his part in this scheme .[48] The Arizona Attorney General, Mark Brnovich, has also filed a lawsuit against Insys in connection with a kickback scheme where Insys paid bribes in the form of sham "speaker fees" to Arizona physicians in exchange for the physicians prescribing Subsys.[49]

187. Further, like tobacco companies, each of the RICO Marketing Participants, also marketed through third-party, unbranded advertising, disseminated by ostensibly "independent" organizations and individuals that the RICO Marketing Participants funded, directed, and controlled—allowing RICO Marketing Participants to carry out and conceal their misconduct, in furtherance of the Opioid Marketing Enterprise.

188. In connection with the Opioid Marketing Enterprise, the Manufacturer Defendants also deceptively marketed opioids in Arizona through ***unbranded advertising***—*i.e.*, advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, each of the RICO Marketing Participants controlled the deceptive messages disseminated by these third parties; acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain;[50] and/or aided and abetted these third parties in promulgating false information about prescription opioids.

189. Moreover, each RICO Marketing Defendant pursued third-party unbranded advertising because they believed it would help them achieve the ends of the Opioid Marketing Enterprise by avoiding regulatory scrutiny. As each RICO Marketing Defendant knew, because unbranded advertising is not submitted to—and typically is not reviewed

---

[48] Emanuel, Gabrielle, *Opioid Executive John Kapoor Found Guilty in Landmark Bribery Case* (May 2, 2019) https://www.npr.org/2019/05/02/711346081/opioid-executive-john-kapoor-found-guilty-in-landmark-bribery-case

[49] *AG Brnovich Files Lawsuit Against Opioid Manufacturer Insys Therapeutics and Three Arizona Doctors*, AZAG.gov (Aug. 31, 2017), https://www.azag.gov/press-release/ag-brnovich-files-lawsuit-against-opioid-manufacturer-insys-therapeutics-and-three.

[50] The phrase "acted in concert" includes conspiring to achieve some end and aiding and abetting in the commission of acts necessary to achieve some end.

by—the FDA, such advertising would create the false appearance that the RICO Marketing Participants' deceptive messages came from an independent, objective source.

190. The Manufacturer Defendants' deceptive unbranded marketing often contradicted what they said in their branded materials reviewed by the FDA. For example, Endo's unbranded advertising contradicted its concurrent, branded advertising for Opana ER:

Pain: Opioid Therapy (Unbranded)	**Opana ER Advertisement (Branded)**
"People who take opioids **as prescribed usually do not become addicted**."	"All patients treated with opioids require careful monitoring for signs of abuse and addiction, since **use of opioid analgesic products carries the risk of addiction even under appropriate medical use**."

3. RICO Marketing Participants Misled Prescribers Through Misleading Training Materials and Key Opinion Leaders (KOLs)

191. In addition to their deceptive opioid advertisements, the Manufacturer Defendants[51] also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by the Manufacturer Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by the Manufacturer Defendants. On information and belief, these presentations conveyed

[51] Upon information and belief, Actavis continued to carry out speaker programs after it acquired Kadian.

misleading information, omitted material information, and failed to correct the Manufacturer Defendants' prior misrepresentations about the risks and benefits of opioids.

192. Indeed, the Manufacturer Defendants also spoke through a small circle of doctors in and around Bullhead City who, upon information and belief, were selected, funded, and elevated by the Manufacturer Defendants because their public positions supported the use of opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs." The Manufacturer Defendants paid these KOLs to serve as consultants or on their advisory boards and to give talks or present continuing medical education programs ("CMEs"), and their support helped these KOLs become respected industry experts. As they rose to prominence, these KOLs touted the benefits of opioids to treat chronic pain, repaying the Manufacturer Defendants by advancing their marketing goals. KOLs' professional reputations became dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by the Manufacturer Defendants.

193. Pro-opioid doctors are one of the most important avenues that the Manufacturer Defendants use to spread their false and misleading statements about the risks and benefits of long-term opioid use for chronic pain. The Manufacturer Defendants know that doctors rely heavily and more uncritically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the New York Attorney General ("NY AG") found in its settlement with Purdue that through March 2015, the Purdue website, "In the Face of Pain," failed to disclose that doctors who provided testimonials on the site were paid by Purdue and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. The Manufacturer Defendants created opportunities for KOLs to participate in research studies Defendants suggested or chose and then cited and promoted favorable studies or articles by their KOLs. By contrast, the Manufacturer Defendants did not support,

acknowledge, or disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

194. The Manufacturer Defendants' KOLs also served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. These guidelines and CMEs were not supported by the scientific evidence at the time they were created, and they are not supported by the scientific evidence today. The Manufacturer Defendants were able to direct and exert control over each of these activities through their KOLs. The 2016 CDC Guideline recognizes that treatment guidelines can "change prescribing practices."

4. RICO Marketing Participants Acted under the Guise of Ostensibly Unbiased, Independent Organizations ("Front Groups")

195. The RICO Marketing Participants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of Defendants, these "Front Groups"—which include, but are not limited to, the American Pain Foundation ("APF"), American Academy of Pain Medicine ("AAPM"), Joint Commission on Accreditation of Healthcare Organizations ("JCAHO"), Federation of State Medical Boards ("FSMB"), Alliance for Patient Access ("APA"), and others—generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. These guidelines, materials, and programs were not supported by the evidence at the time they were created, and they are not supported by the scientific evidence today. Indeed, they stand in marked contrast to the 2016 CDC Guideline. These Front Groups also assisted the RICO Marketing Participants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

196. These Front Groups depended on the RICO Marketing Participants for funding

and, in some cases, for survival. As detailed below, Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination.

197. In doing so, the RICO Marketing Participants made sure the Groups would generate only the messages the RICO Marketing Participants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members—whether patients suffering from pain or doctors treating those patients.

(a) American Pain Foundation ("APF")

198. The American Pain Foundation: The American Pain Foundation ("APF") described itself as the nation's largest organization for pain patients.[52] While APF held itself out as an independent patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and medical-device industry, including from defendants Purdue, Endo, Janssen and Cephalon. It received more than $10 million in funding from opioid manufacturers from 2007 to 2012, when it shut down days after the U.S. Senate Committee on Finance ("Senate Finance Committee") launched an investigation of the APF's promotion of prescription opioids.

199. The APF's guides for patients, journalists and policymakers trivialized the risk of addiction and greatly exaggerated the benefits associated with opioid painkillers.[53]

200. For example, in 2001, APF published "Treatment Options: A Guide for People Living with Pain."[54] The guide, which was produced due to support from companies including defendants Cephalon and Purdue, misrepresented the risks associated with opioid

[52] The APF was the focus of a December investigation by ProPublica in the Washington Post that detailed its close ties to drugmakers

[53] Charles Ornstein & Tracy Weber, *American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics*, ProPublica (May 8, 2012, 8:57 PM), https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-paingroups (hereinafter "Ornstein, American Pain Foundation").

[54] *Treatment Options: A Guide for People Living with Pain*, American Pain Foundation, https://assets.documentcloud.org/documents/277605/apf-treatment options.pdf (last visited Mar. 11, 2018).

use. Among other things, the guide:

- lamented that opioids were sometimes called narcotics because "[c]alling opioid analgesics 'narcotics' reinforces myths and misunderstandings as it places emphasis on their potential abuse rather than on the importance of their use as pain medicines";[55]

- stated that "[o]pioids are an essential option for treating moderate to severe pain associated with surgery or trauma";[56] and

- opined that "[r]estricting access to the most effective medications for treating pain [opioids] is not the solution to drug abuse or addiction."[57]

The guide included blurbs from Portenoy, who is quoted as saying "[t]his is a very good resource for the pain patient," and Fishman, who is quoted as saying, "[w]hat a great job! Finally, a pill consumer resource created for patients with pain. A 'must have' for every physician's waiting room."[58]

201. In 2003, APF published a newsletter titled "Best of . . . The Pain Community News" that purported to clarify any confusion over addiction and opioids and emphasized the "tragic consequence of leaving many people with severe pain under-treated because they—or their doctors—fear that opioids will cause addiction."

202. In 2009, Endo sponsored APF's publication and distribution of "Exit Wounds: A Survival Guide to Pain Management for Returning Veterans & Their Families" ("Exit Wounds"), a book described as "the inspirational story of how one courageous veteran, with the aid of his family, recovered and thrived despite near death, traumatic brain injury, and the loss of a limb." It also purported to "offer[] veterans and their families comprehensive and authoritative information on . . . treatment options, and strategies for self-advocating for optimal pain care and medical resources inside and outside the VA system."

203. Among other false statements, Exit Wounds reported: "Long experience with

---

[55] *Id.* at 11.

[56] *Id.*

[57] *Id.* at 15.

[58] *Id.* at 76.

opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." Endo, through APF, thus distributed false information with the purpose of providing veterans false information they could use to "self-advocat[e]" for opioids while omitting a discussion of the risks associated with opioid use.

204. In 2009, APF played a central role in a first-of-its-kind web-based series called "Let's Talk Pain," hosted by veteran TV journalist Carol Martin. The series brought together healthcare providers and "people with pain to discuss a host of issues from managing health care for pain to exploring integrative treatment approaches to addressing the psychological aspects associated with pain." The "Let's Talk Pain" talk show is still available online. In the very first episode of this talk show, the following exchange took place:

> [Teresa Shaffer (APF Action Network Leader):] As a person who has been living with pain for over 20 years, opioids are a big part of my pain treatment. And I have been hearing such negative things about opioids and the risk factors of opioids. Could you talk with me a little bit about that?
>
> [Dr. Al Anderson (AAPM Board of Directors):] The general belief system in the public is that the opioids are a bad thing to be giving a patient. Unfortunately, it's also prevalent in the medical profession, so patients have difficulty finding a doctor when they are suffering from pain for a long period of time, especially moderate to severe pain. And that's the patients that we really need to use the opioids methods of treatment, because they are the ones who need to have some help with the function and they're the ones that need to be controlled enough so that they can increase their quality of life.[59]

205. In reality, there is little scientific evidence to support the contention that opioids taken long-term improve function or quality of life for chronic pain patients.[60] To the contrary, there is ample evidence that opioids impose significant risks and adverse outcomes on long-term users and may actually reduce function.[61]

---

[59] *Episode 1: Safe Use of Opioids (PainSAFE), Let's Talk Pain* (Sept. 28, 2010), https://www.youtube.com/watch?v=zeAlVAMRgsk&t=39s.

[60] Lembke (2016), *supra*, at 59 (citing *The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain, Evidence Report/Technology Assessment*, No. 218, Agency for Healthcare Research and Quality (Sept. 2014), https://effectivehealthcare.ahrq.gov/sites/default/files/related_files/chronic-pain-opioid-treatment_executive.pdf)

[61] Discussing the CDC's "*March 2016 Guideline for Prescribing Opioids for Chronic Pain*," doctors wrote:

206. As a recent article in the New England Journal of Medicine concluded: "Although opioid analgesics rapidly relieve many types of acute pain and improve function, the benefits of opioids when prescribed for chronic pain are much more questionable." The article continues, "opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions."[62]

207. The APF also developed the National Initiative on Pain Control ("NIPC"), which ran a facially unaffiliated website called www.painknowledge.org. NIPC promoted itself as an education initiative and promoted its expert leadership team, including purported experts in the pain management field. The website painknowledge.org promised that, on opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. In a brochure available on painknowledge.org titled "Pain: Opioid Facts," the NIPC misleadingly stated that "people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted" and even refused to rule out the use of opioid

---

> Most placebo-controlled, randomized trials of opioids have lasted 6 weeks or less, and we are aware of no study that has compared opioid therapy with other treatments in terms of long-term (more than 1 year) outcomes related to pain, function, or quality of life. The few randomized trials to evaluate opioid efficacy for longer than 6 weeks had consistently poor results. In fact, several studies have showed that use of opioids for chronic pain may actually worsen pain and functioning, possibly by potentiating pain perception.

Thomas R. Frieden & Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, 374 NEW ENG. J. MED. 1501-04 (Apr. 21, 2016), http://www.nejm.org/doi/full/10.1056/NEJMp1515917?af=R&rss=currentIssue&#t=article (footnote omitted).

[62] Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies*, 374 NEW ENG. J. MED. 1253-63 (Mar. 31, 2016), http://www.nejm.org/ doi/full/10.1056/NEJMra1507771#t=article

pain relievers for patients who have a history of addiction to opioids.[63]

208. In or around 2011, the APF published the "Policymaker's Guide," sponsored by Purdue, which dispelled the notion that "strong pain medication leads to addiction" by characterizing it as a "common misconception[]":

> Many people living with pain, and even some health care practitioners, falsely believe that opioid pain medicines are universally addictive. As with any medication, there are risks, but these risks can be managed when these medicines are properly prescribed and taken as directed. For more information about safety issues related to opioids and other pain therapies, visit http://www.painsafe.org.76[64]

209. The guide describes "pain in America" as "an evolving public health crisis" and characterizes concerns about opioid addiction as misconceptions: "Unfortunately, too many Americans are not getting the pain care they need and deserve. Some common reasons for difficulty in obtaining adequate care include: . . . Misconceptions about opioid addiction."[65] It even characterizes as a "myth" that "[c]hildren can easily become addicted to pain medications."[66] The guide further asserts that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health and health-related quality of life for chronic pain patients, which was not the case.[67]

210. In December 2011, the Washington Post reported on ProPublica's

---

[63] *Pain: Opioid Facts, Pain Knowledge* https://web.archive.org/web/20101007102042/http://painknowledge.org/patiented/pdf/Patient%20Education%20b 380_b385%20%20pf%20opiod.pdf (last visited Mar. 11, 2018).

[64] A Policymaker's Guide to Understanding Pain & Its Management, American Pain Foundation at 5 (Oct. 2011), http://s3.documentcloud.org/documents/277603/apfpolicymakers-guide.pdf.

[65] *Id*. at 6.

[66] *Id.* at 40.

[67] The "Policymaker's Guide" cites for support "Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects," a review published in 2006 in the Canadian Medical Association Journal. *Id.* at 34. However, the review concludes: "For functional outcomes, the other analgesics were significantly more effective than were opioids." Andrea D. Furlan, et al., Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects, 174(11) CANADIAN MED. ASSOC. J. 1589-94 (May 23, 2006), https://www.ncbi.nlm.nih.gov/ pmc/articles/PMC1459894/. The Purdue-sponsored guide failed to disclose both this conclusion and the fact that the review analyzed studies that lasted, on average, five weeks and therefore could not support the long-term use of opioids

investigation of the APF, which detailed APF's close ties to drugmakers: [T]he pills continue to have an influential champion in the American Pain Foundation, which describes itself as the nation's largest advocacy group for pain patients. Its message: The risk of addiction is overblown, and the drugs are underused. What the nonprofit organization doesn't highlight is the money behind that message. The foundation collected nearly 90 percent of its $5 million in funding last year from the drug and medical-device industry – and closely mirrors its positions, an examination by ProPublica found.[68]

211. In 2010 alone, the APF received 90% of its funding from drug and medical device companies, including from Purdue. Purdue paid APF unspecified amounts in 2008 and 2009 and between $100,000 and $499,999 in 2010.[69]

212. Later, in 2014, Endo issued a patient brochure titled "Understanding Your Pain: Taking Oral Opioid Analgesics." It was written by nurses Margo McCaffery and Chris Pasero and edited by APF board member Portenoy.

213. Endo, along with Janssen and Purdue, also provided grants to APF to distribute Exit Wounds, discussed above.[70]

214. The Senators demanded substantial discovery, including payment information from the companies to various groups, including the front organizations identified above, and to physicians, including Portenoy, Fishman and Fine, among others. They asked about

---

[68] Charles Ornstein & Tracy Weber, *Patient advocacy group funded by success of painkiller drugs, probe finds*, WASH. POST (Dec. 23, 2011), https://www.washingtonpost.com/national/health-science/patient-advocacy-group-funded-by-success-of-painkiller-drugsprobe-finds/2011/12/20/gIQAgvczDP_story.html?utm_term=.22049984c606

[69] American Pain Foundation Partner Report, *GuideStar*, http://www.guidestar.org/PartnerReport.aspx?ein=52-2002328&Partner=Demo.

[70] Iraq War Veteran Amputee, *Pain Advocate and New Author Release Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families*, Coalition for Iraq + Afghanistan Veterans, https://web.archive.org/web/20160804131030/http://coalitionforveterans.org/2009/10/iraq-war-veteran-amputee-pain-advocate-and-newauthor-releases-exit-wounds-a-survival-guide-to-pain-management-for-returning-veteransand-their-families/ (last visited Mar. 11, 2018)

any influence the companies had on a 2004 pain guide for physicians that was distributed by the FSMB, on the APS' guidelines and on the APF's Military/Veterans Pain Initiative. Almost immediately upon the launch of the Senate investigation, the APF shut down "due to irreparable economic circumstances." The opioid report resulting from this investigation has not been released publicly.[71]

215. On March 29, 2017, it was widely reported114[72] that yet another Senate investigation had been launched.

216. Purdue also deceptively marketed the use of opioids for chronic pain through the APF, which was shut down after the Senate investigation launched in 2012. In 2010 alone, the APF received 90% of its funding from drug and medical device companies, including from Purdue. Purdue paid APF unspecified amounts in 2008 and 2009 and between $100,000 and $499,999 in 2010.[73]

217. Like several of the other Manufacturer Defendants, Endo provided substantial funding to purportedly neutral medical organizations, including APF.

218. For example, in April 2007, Endo sponsored an article aimed at prescribers, written by Dr. Charles E. Argoff in Pain Medicine News, titled "Case Challenges in Pain Management: Opioid Therapy for Chronic Pain."[74]

219. The article commenced with the observation that "[a]n estimated 50 to 60 million people . . . suffer from chronic pain." It continued: Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for

---

[71] Paul D. Thacker, *Senators Hatch and Wyden: Do your jobs and release the sealed opioids report*, Stat News (June 27, 2016), https://www.statnews.com/ 2016/06/27/opioidaddiction-orrin-hatch-ron-wyden/; see also Ornstein, American Pain Foundation, *supra*, n. 56.

[72] Suzanne Elvidge, *Senators launch investigation into opioid manufacturers*, BioPharmaDive.com (Mar. 29, 2017), available at https://www.biopharmadive.com/news/senators-launch-investigation-into-opioid-manufacturers/439248/

[73] American Pain Foundation Partner Report, *GuideStar*, http://www.guidestar.org/

[74] Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*, Pain Med. News, http://www.painmedicinenews.com/download/BtoB_Opana_WM.pdf.

controlling both chronic and acute pain. The phenomenon of tolerance to opioids – the gradual waning of relief at a given dose – and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.[75]

220. The article included a case study that focused on the danger of extended use of NSAIDs, including that the subject was hospitalized with a massive upper gastrointestinal bleed believed to have resulted from his protracted NSAID use. In contrast, the article did not provide the same detail concerning the serious side effects associated with opioids. It concluded by saying that "use of opioids may be effective in the management of chronic pain."

221. Later, in 2014, Endo issued a patient brochure titled "Understanding Your Pain: Taking Oral Opioid Analgesics." It was written by nurses Margo McCaffery and Chris Pasero and edited by APF board member Portenoy.

222. The brochure included numerous false and misleading statements minimizing the dangers associated with prescription opioid use. Among other things, the brochure falsely and misleadingly represented that:

> Addiction IS NOT when a person develops "withdrawal" (such as abdominal cramping or sweating) after the medicine is stopped quickly or the dose is reduced by a large amount. Your doctor will avoid stopping your medication suddenly by slowly reducing the amount of opioid you take before the medicine is completely stopped. Addiction also IS NOT what happens when some people taking opioids need to take a higher dose after a period of time in order for it to continue to relieve their pain. This normal "tolerance" to opioid medications doesn't affect everyone who takes them and does not, by itself, imply addiction. If tolerance does occur, it does not mean you will "run out" of pain relief. Your dose can be adjusted or another medicine can be prescribed.
>
> * * *
>
> How can I be sure I'm not addicted?
>
> - Addiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don't need it for pain, maybe just to escape from your problems.

[75] *Id.*

- Ask yourself: Would I want to take this medicine if my pain went away? If you answer no, you are taking opioids for the right reasons – to relieve your pain and improve your function. You are not addicted.

* * *

Your doctor or nurse may instruct you to do some of the following: Take the next dose before the last dose wears off. If pain is present most of the day and night, the pain medicine may be taken at regularly scheduled times. If you are taking a short-acting opioid, this usually means taking it every 4 hours. You may need to set your alarm especially at night, to be sure you take your dose before the pain returns and wakes you up.

- If your pain comes and goes, take your pain medicine when pain first begins, before it becomes severe.

- If you are taking a long-acting opioid, you may only need to take it every 8 to 12 hours, but you may also need to take a short-acting opioid in between for any increase in pain.[76]

223. In 2008, Endo also provided an "educational grant" to PainEDU.org, which produced a document titled "Screener and Opioid Assessment for Patients with Pain ("SOAPP") Version 1.0-14Q." Endo and King Pharmaceuticals sponsor PainEDU.org.188[77] SOAPP describes itself "as a tool for clinicians to help determine how much monitoring a patient on long-term opioid therapy might require." It falsely highlights purportedly "recent findings suggesting that most patients are able to successfully remain on long-term opioid therapy without significant problems."

224. Endo also sponsored the now-defunct website painknowledge.com, which was created by APF and stated it was "a one-stop repository for print materials, educational resources, and physician tools across the broad spectrum of pain assessment, treatment, and

[76] Margo McCaffery & Chris Pasero, *Understanding Your Pain: Taking Oral Opioid Analgesics*, Endo Pharmaceuticals (2004), available at http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf (emphasis in original).

[77] B. Eliot Cole, *Resources for Education on Pain and Its Management: A Practitioner's Compendium* 2 (Am. Society of Pain Educators 2009), available at https://www.paineducators.org/wpcontent/uploads/2012/12/ASPE-ResForEducationOnPainAn.pdf.

management approaches."[78] Among other featured content, painknowledge.com included a flyer titled "Pain: Opioid Therapy," which failed to warn of significant adverse effects that could arise from opioid use, including hyperalgesia, immune and hormone dysfunction, cognitive impairment, decreased tolerance, dependence and addiction.

225. Endo, along with Janssen and Purdue, also provided grants to APF to distribute Exit Wounds, discussed above.[79]

226. Fine authored a Cephalon-sponsored CME presentation titled "Opioid-Based Management of Persistent and Breakthrough Pain," with Drs. Christine A. Miaskowski and Michael J. Brennan. Cephalon paid to have this CME presentation published as a "Special Report" supplement of the journal Pain Medicine News in 2009.[80] The CME presentation targeted a wide variety of non-oncologist healthcare providers who treat patients with chronic pain with the objective of educating "health care professionals about a semi-structured approach to the opioid-based management of persistent and breakthrough pain," including the use of fentanyl. The CME presentation purports to analyze the "combination of evidence- and case-based discussions" and ultimately concludes: Chronic pain is a debilitating biopsychosocial condition prevalent in both cancer and noncancer pain populations. . . . Opioids have an established role in pain related to cancer and other advanced medical illnesses, as well as an increasing contribution to the long-term treatment of carefully selected and monitored patients with certain [chronic noncancer pain] conditions. All individuals with chronic, moderate to severe pain associated with functional impairment should be considered for a trial or opioid therapy, although not all of them will be selected.[81]

---

[78] AboutPainKnowledge.org, *PainKnowledge*, http://web.archive.org/web/20120119124921/http://www.painknowledge.org/aboutpaink.aspx (last visited Mar. 11, 2018).

[79] Iraq War Veteran Amputee, *supra* , at n. 73.

[80] Perry G. Fine, et al., *Opioid-Based Management of Persistent and Breakthrough Pain, Special Report* (2009), https://www.yumpu.com/en/document/view/11409251/opioid-basedmanagement-of-persistent-and-breakthrough-pain/9.

[81] *Id.*

227. Along with Purdue, Cephalon sponsored APF's guide, which warned against the purported under-prescribing of opioids, taught that addiction is rare and suggested that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain.

228. A summary of the February 12-16, 2008 AAPM annual meeting reinforced the message, promoted both by the AAPM and the APS, that "the undertreatment of pain is unjustified." It continues: Pain management is a fundamental human right in all patients not only with acute postoperative pain but also in patients suffering from chronic pain. Treating the underlying cause of pain does not usually treat all of the ongoing pain. Minimal pathology with maximum dysfunction remains the enigma of chronic pain. Chronic pain is only recently being explored as a complex condition that requires individual treatment and a multidisciplinary approach. It is considered to be a disease entity.[82]

229. Cephalon was one of several opioid manufacturers who collectively paid 14 of the 21 panel members who drafted the 2009 APS-AAPM opioid treatment guidelines.[83]

230. In the March 2007 article titled "Impact of Breakthrough Pain on Quality of Life in Patients with Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment with Oral Transmucosal Fentanyl Citrate,"[84] published in the nationally circulated journal Pain Medicine, physicians paid by Cephalon (including Webster) described the results of a Cephalon-sponsored study seeking to expand the definition of BTP to the chronic, non-cancer setting. The authors stated that the "OTFC has been shown to relieve BTP more rapidly than conventional oral, normal-release, or 'short acting' opioids" and that "[t]he purpose of [the] study was to provide a qualitative evaluation of the effect of BTP on the

---

[82] Mohamed A. Elkersh & Zahid H. Bajwa, *Highlights From the American Academy of Pain Medicine 24th Annual Meeting*, 2(1) Advances in Pain Management 50-52 (2008).

[83] *See* Chou, *Clinical Guidelines*, supra n. 102.

[84] Donald R. Taylor, et al., *Impact of Breakthrough Pain on Quality of Life in Patients With Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment With Oral Transmucosal Fentanyl Citrate* (OTFC, ACTIQ), 8(3) Pain Med. 281-88 (Mar. 2007)

quality of life] of noncancer pain patients."[85]. The number-one-diagnosed cause of chronic pain in the patients studied was back pain (44%), followed by musculoskeletal pain (12%) and head pain (7%). The article cites Portenoy and recommends fentanyl for non-cancer BTP patients:

> In summary, BTP appears to be a clinically important condition in patients with chronic noncancer pain and is associated with an adverse impact on QoL. This qualitative study on the negative impact of BTP and the potential benefits of BTP-specific therapy suggests several domains that may be helpful in developing BTP-specific, QoL assessment tools.[86]

231. Cephalon also sponsored, through an educational grant, the regularly published journal Advances in Pain Management. In a single 2008 issue of the journal, there are numerous articles from Portenoy, Dr. Steven Passik ("Passik"), Dr. Kenneth L. Kirsh ("Kirsh") and Webster, all advancing the safety and efficacy of opioids. In an article titled "Screening and Stratification Methods to Minimize Opioid Abuse in Cancer Patients," Webster expresses disdain for the prior 20 years of opioid phobia.

232. In another article from the same issue, "Appropriate Prescribing of Opioids and Associated Risk Minimization," Passik and Kirsh state: "[c]hronic pain, currently experienced by approximately 75 million Americans, is becoming one of the biggest public health problems in the US." They assert that addiction is rare, that "[m]ost pain specialists have prescribed opioids for long periods of time with success demonstrated by an improvement in function" and that then-recent work had shown "that opioids do have efficacy for subsets of patients who can remain on them long term and have very little risk of addiction."[87]

233. In November 2010, Fine and others published an article presenting the results of another Cephalon-sponsored study titled "Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with

---

[85] *Id.*

[86] *Id.*

[87] Steven D. Passik & Kenneth L. Kirsh, *Appropriate Prescribing of Opioids and Associated Risk Minimization*, 2(1) ADVANCES IN PAIN MANAGEMENT 9-16 (2008).

Chronic Pain: An 18-Month Study."[88] In that article, Fine explained that the 18-month "open-label" study "assessed the safety and tolerability of FBT [Fentora] for the [long term] treatment of BTP in a large cohort . . . of opioid-tolerant patients receiving around the-clock . . . opioids for noncancer pain." The article acknowledged that: (a) "[t]here has been a steady increase in the use of opioids for the management of chronic noncancer pain over the past two decades"; (b) the "widespread acceptance" had led to the publishing of practice guidelines "to provide evidence- and consensus-based recommendations for the optimal use of opioids in the management of chronic pain"; and (c) those guidelines lacked "data assessing the long-term benefits and harms of opioid therapy for chronic pain."[89].

234. The article concluded: "[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable, manageable, and tolerable." They also conclude that the number of abuse-related events was "small."[90]

235. From 2000 forward, Cephalon has paid doctors nationwide millions of dollars for programs relating to its opioids, many of whom were not oncologists and did not treat cancer pain. These doctors included Portenoy, Webster, Fine, Passik, Kirsh, Landy and others.

236. Cephalon's payments to doctors have resulted in studies that support its sales but, on closer examination, are biased or irreparably flawed. For instance, and upon information and belief, the governmental whistleblower investigation into Actiq revealed that two studies touted by Cephalon had tested fewer than 28 patients and had no control group whatsoever.[91] A 2012 article evaluating the then-current status of transmucosal fentanyl tablet formulations for the treatment of BTP in cancer patients noted that clinical

---

[88] Perry G. Fine, et al., *Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study*, 40(5) J. PAIN & SYMPTOM MANAGEMENT 747-60 (Nov. 2010).

[89] *Id.*

[90] *Id.*

[91] Carreyrou, *Cephalon Used Improper Tactics*.

trials to date used varying criteria, that "the approaches taken . . . [did] not uniformly reflect clinical practice" and that "the studies ha[d] been sponsored by the manufacturer and so ha[d] potential for bias."[92]

237. Teva, which acquired Cephalon, has repeatedly refused to produce information requested as part of a Senate investigation into opioid manufacturers and distributors. Senator McCaskill issued requests on July 26, 2017 and September 28, 2017. In a letter to Teva sent September 28, 2017, Senator McCaskill explained that "the company's decision to obstruct basic oversight on the opioid epidemic should deeply concern shareholders." On March 6, 2018, Senator McCaskill issued a press release castigating Teva for its continued refusal to comply with her requests: "Teva's refusal to cooperate with Congressional requests strongly suggests they have something to hide."

238. For example, Purdue's consulting agreement with APF gave it direct, contractual control over APF's work. The Manufacturer Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, the Manufacturer Defendants combined their efforts through the Pain Care Forum ("PCF"), which began in 2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Endo, Janssen/J&J, and Purdue) and various Front Groups, almost all of which received substantial funding from the Manufacturer Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which the Manufacturer Defendants determined would reduce prescribing. PCF also worked to address a perceived "lack of coordination" among its members and developed "key" messages that were disseminated in programs and industry-run websites.

---

[92] Eric Prommer & Brandy Fleck, *Fentanyl transmucosal tablets: current status in the management of cancer-related breakthrough pain*, 2012(6) PATIENT PREFERENCE AND ADHERENCE 465-75 (June 25, 2012).

(b) Joint Commission on Accreditation of Healthcare Organizations ("JCAHO")

239. JCAHO is an organization that establishes standards for treatment and accredits healthcare organizations in the United States. The Manufacturing Defendants, including Purdue, contributed misleading and groundless teaching materials and videos to the Joint Commission, which emphasized what Big Pharma coined the "under-treatment of pain," referenced pain as the "fifth vital sign" (the first and only unmeasurable/subjective vital sign) that must be monitored and treated, and encouraged the use of prescription opioids for chronic pain while minimizing the danger of addiction. It also called doctors' concerns about addiction "inaccurate and exaggerated."

240. In 2000, the Joint Commission printed a book for purchase by doctors as part of required continuing education seminars that cited studies claiming "there is no evidence that addiction is a significant issue when persons are given opioids for pain control." The book was sponsored by Purdue.

241. In 2001, the Joint Commission and the National Pharmaceutical Council ("JCAHO"), which was founded in 1953 and supported by the nation's major research-based biopharmaceutical companies,[93] collaborated to issue a 101-page monograph titled "Pain: Current understanding of assessment, management, and treatments." The monograph states falsely that beliefs about opioids being addictive are "erroneous":

> Societal issues that contribute to the undertreatment of pain include drug nabuse programs and erroneous beliefs about tolerance, physical dependence, and addiction (see I.E.5). For example, some clinicians incorrectly assume that exposure to an addictive drug usually results in addiction.
>
> * * *
>
> b. Etiology, issues, and concerns
>
> Many medications produce tolerance and physical dependence, and some (e.g., opioids, sedatives, stimulants, anxiolytics, some muscle relaxants) may cause addiction in vulnerable individuals. Most experts agree that patients who undergo prolonged opioid therapy usually develop physical dependence but do not develop

[93] Currently funded by Johnson & Johnson, Purdue and Teva, among others.

> addictive disorders. In general, patients in pain do not become addicted to opioids. Although the actual risk of addiction is unknown, it is thought to be quite low. A recent study of opioid analgesic use revealed "low and stable" abuse of opioids between 1990 and 1996 despite significant increases in opioids prescribed. . . . Fear of causing addiction (i.e., iatrogenic addiction), particularly with opioid use, is a major barrier to appropriate pain management. This fear sometimes reflects a lack of understanding of the risk of addiction with therapeutic drug use. Although studies suggest that the risk of iatrogenic addiction is quite low (e.g., Perry and Heidrich, Zenz et al.), surveys indicate that clinicians often overestimate this risk.[94]

242. Additionally, the monograph recommends that "[p]ain . . . [be] assessed in all patients" and suggests that long-acting (i.e., extended release) pain medications are superior and should be used whenever possible:

> Long-acting and sustained-release opioids are useful for patients with continuous pain, as they lessen the severity of end-of-dose pain and often allow the patient to sleep through the night.
>
> * * *

In truth, such medications often do not last as long as promised, and there is evidence to suggest that the use of long-acting drugs may actually create more addicts.

- Administer opioids primarily via oral or transdermal routes, using longacting medications when possible.[95]

243. The Manufacturing Defendants' infiltration and influence over the Joint Commission's standards and literature exerted overwhelming pressure on doctors to treat and eliminate pain. As more and more doctors migrated from private practice to integrated healthcare systems in the 2000s, treatment options were dictated by, among other things, the Joint Commission's guidelines.[96] Consistent with the guidelines, doctors who left pain untreated were viewed as demonstrating poor clinical skills and/or being morally compromised.[97]

---

[94] *Pain: Current Understanding of Assessment, Management, and Treatments* at 16-17 (Dec. 2001), http://www.npcnow.org/system/files/research/download/Pain-Current-Understanding-of-Assessment-Management-and-Treatments.pdf (footnotes and citations omitted).

[95] *Id.* at 38, 67 (Table 38).

[96] Lembke (2016), *supra* n. 63, at 119.

[97] *Id.* at 42.

244. The U.S. General Accounting Office's December 2003 Report to Congressional Requesters confirms that Purdue funded the "pain management educational courses" that taught the new standard of care for treating pain. It further revealed that Purdue disseminated educational materials on pain management, which "'facilitated [Purdue's] access to hospitals to promote OxyContin.'"[98]

(c) The American Academy of Pain Medicine ("AAPM") and The American Pain Society ("APM")

245. American Academy of Pain Medicine and American Pain Society: The Manufacturing Defendants, including at least Endo, Janssen and Purdue, have contributed funding to the AAPM and the APS for decades.

246. In 1997, the AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The chairman of the committee that issued the statement, Haddox, was, at the time, a paid speaker for Purdue. Haddox was later hired as Purdue's vice president for health policy. The consensus statement, which also formed the foundation of the 1998 guidelines, was published on the AAPM's website. AAPM's corporate council includes Purdue, Depomed, Inc. ("Depomed"), Teva and other pharmaceutical companies. AAPM's past presidents include Haddox (1998), Fishman (2005), Dr. Perry G. Fine ("Fine") (2011) and Lynn R. Webster ("Webster") (2013), all of whose connections to the opioid manufacturers are well-documented as set forth below.

247. At or about the same time, the APS introduced the "pain as the 5th vital sign" campaign, followed soon thereafter by Veterans Affairs adopting that campaign as part of their national pain management strategy.

248. AAPM and APS issued guidelines in 2009 ("2009 Guidelines") that continued

[98] Gounder, *Who Is Responsible*, *supra*, n.40; U.S. General Accounting Office, GAO-04-110, *Prescription Drugs, OxyContin Abuse and Diversion and Efforts to Address the Problem* (Dec. 2003), available at http://www.gao.gov/new.items/d04110.pdf.

to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines received funding from defendants Janssen, Cephalon, Endo or Purdue.

249. The 2009 Guidelines falsely promoted opioids as safe and effective for treating chronic pain and concluded that the risk of addiction was manageable for patients regardless of past abuse histories.[99] The 2009 Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians but also the body of scientific evidence on opioids; they were reprinted in the journal Pain, have been cited hundreds of times in academic literature and remain available online. The Manufacturing Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions.

(d) The Alliance for Patient Access ("APA")

250. Founded in 2006, the Alliance for Patient Access ("APA") is a self-described patient advocacy and health professional organization that styles itself as "a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care."[100] It is run by Woodberry Associates LLC, a lobbying firm that was also established in 2006.[101] As of June 2017, the APA listed 30 "Associate Members and Financial Supporters." The list includes Johnson & Johnson, Endo, Mallinckrodt, Purdue and Cephalon.

---

[99] Roger Chou, et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10(2) J. Pain 113-30 (Feb. 2009), http://www.jpain.org/article/S1526-5900(08)00831-6/pdf (hereinafter "Chou, Clinical Guidelines").

[100] About AfPA, *The Alliance for Patient Access*, available at http://allianceforpatientaccess.org/aboutafpa/#membership. References herein to APA include two affiliated groups: the Global Alliance for Patient Access and the Institute for Patient Access

[101] Mary Chris Jaklevic, *Non-profit Alliance for Patient Access uses journalists and politicians to push Big Pharma's agenda*, HEALTH NEWS REVIEW (Oct. 2, 2017), https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-usesjournalists-politicians-push-big-pharmas-agenda/ (hereinafter "Jaklevic, Non-profit Alliancefor Patient Access").

251. APA's board members have also directly received substantial funding from pharmaceutical companies.[102] For instance, board vice president Dr. Srinivas Nalamachu ("Nalamachu"), who practices in Kansas, received more than $800,000 from 2013 through 2015 from pharmaceutical companies – nearly all of it from manufacturers of opioids or drugs that treat opioids' side-effects, including from defendants Endo, Insys, Purdue and Cephalon. Nalamachu's clinic was raided by Federal Bureau of Investigation ("FBI") agents in connection with an investigation of Insys and its payment of kickbacks to physicians who prescribed Subsys.[103] Other board members include Dr. Robert A. Yapundich from North Carolina, who received $215,000 from 2013 through 2015 from pharmaceutical companies, including payments by defendants Cephalon and Mallinckrodt; Dr. Jack D. Schim from California, who received more than $240,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Mallinckrodt and Cephalon; Dr. Howard Hoffberg from Maryland, who received $153,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Purdue, Insys, Mallinckrodt and Cephalon; and Dr. Robin K. Dore from California, who received $700,000 between 2013 and 2015 from pharmaceutical companies.

252. Among its activities, APA issued a white paper titled "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse."[104] Among other things, the white paper criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user friendly, and of questionable efficacy:

---

[102] All information concerning pharmaceutical company payments to doctors in this paragraph is from ProPublica's *Dollars for Docs* database, available at https://projects.propublica.org/docdollars/

[103] Andy Marso, *FBI seizes records of Overland Park pain doctor tied to Insys*, Kansas City Star (July 20, 2017), available at http://www.kansascity.com/news/business/health-care/article162569383.html.

[104] *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse, Institute for Patient Access* (Oct. 2013), available at http://1yh21u3cjptv3xjder1dco9mx5s.wpengine.netdnacdn.com/wp-content/uploads/2013/12/PT_White-Paper_Finala.pdf

> Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief medications elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal.
>
> * * *
>
> In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover, threatening and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives. . . . We cannot merely assume that these programs will reduce prescription pain medication use and abuse.[105]

253. The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:

> Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements. . . . [I]t is not even certain that the regulations are helping prevent abuses.[106]

254. In addition, in an echo of earlier industry efforts to push back against what they termed "opiophobia," the white paper laments the stigma associated with prescribing and taking pain medication:

> Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can't get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong – or even criminal. . . . Physicians can face similar stigma from peers. Physicians in non-pain specialty areas often look down on those who specialize in pain management – a situation fueled by the numerous regulations and fines that surround prescription pain medications.[107]

255. Further, the white paper notes that "[p]rescription pain medications, and specifically the opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other

---

[105] *Id.* at 4-5 (footnote omitted).

[106] *Id.* at 5-6.

[107] *Id.* at 6

conditions that does not adequately respond to over-the-counter drugs."[108]

256. The APA also publishes "Patient Access Champion" financial awards to members of Congress, including 50 such awards in 2015. The awards were funded by a $7.8 million donation from unnamed donors. While the awards are ostensibly given for protecting patients' access to Medicare, and are thus touted by their recipients as demonstrating a commitment to protecting the rights of senior citizens and the middle class, they appear to be given to provide cover to and reward members of Congress who have supported the APA's agenda.[109]

257. The APA also lobbies Congress directly. In 2015, the APA signed onto a letter supporting legislation proposed to limit the ability of the DEA to police pill mills by enforcing the "suspicious orders" provision of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §801 et seq. ("CSA" or "Controlled Substances Act").92[110] The AAPM is also a signatory to this letter. An internal DOJ memo stated that the proposed bill "'could actually result in increased diversion, abuse, and public health and safety consequences'"93[111] and, according to DEA chief administrative law judge John J. Mulrooney. "Mulrooney"), the law would make it "all but logically impossible" to defend prosecutions of manufacturers and distributors, like the defendants here, in the federal courts.[112] The law passed both houses of Congress and was signed into law in 2016.

---

[108] *Id.* at 7.

[109] Jaklevic, *Non-profit Alliance for Patient Access, supra* n. 104.

[110] *Letter from Alliance for Patient Access, et al., to Congressmen Tom Marino, Marsha Blackburn, Peter Welch, and Judy Chu* (Jan. 26, 2015), available at http://www.hoparx.org/images/hopa/advocacy/advocacy-activities/FINAL_Patient_Access_Letter_of_Support_House_Bill.pdf.

[111] Bill Whitaker, *Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress*, CBS News (Oct. 17, 2017), available at https://www.cbsnews.com/news/ex-dea-agent-opioid-crisisfueled-by-drug-industry-and-congress/ (hereinafter, "Whitaker, Opioid Crisis Fueled by Drug Industry").

[112] John J. Mulrooney, II & Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101(2) MARQUETTE L. REV. 333-451 (Winter 2017), available at

(e) The Federation of State Medical Boards ("FSMB")

258. The Federation of State Medical Boards: The Federation of State Medical Boards ("FSMB") is a national organization that functions as a trade group representing the 70 medical and osteopathic boards in the United States. The FSMB often develops guidelines that serve as the basis for model policies with the stated goal of improving medical practice. Defendants Purdue, Cephalon, and Endo have provided substantial funding to the FSMB. Among its members are the Arizona Medical Board and the Arizona Board of Osteopathic Examiners in Medicine and Surgery.

259. In 2007, the FSMB printed and distributed a physician's guide on the use of opioids to treat chronic pain titled "Responsible Opioid Prescribing" by Dr. Scott M. Fishman ("Fishman"). After the guide (in the form of a book, still available for sale on Amazon) was adopted as a model policy, the FSMB reportedly asked Purdue for $100,000 to help pay for printing and distribution. Ultimately, the guide was disseminated by the FSMB to 700,000 practicing doctors, including thousands in Arizona.

260. The guide's clear purpose is to focus prescribers on the purported under-treatment of pain and falsely assure them that opioid therapy is an appropriate treatment for chronic, non-cancer pain.

- Pain management is integral to good medical practice and for all patients;
- Opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and noncancer origins;
- Patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient.

* * *

Four key factors contribute to the ongoing problem of under-treated pain:

1. Lack of knowledge of medical standards, current research, and clinical guidelines for appropriate pain treatment;

2. The perception that prescribing adequate amounts of opioids will result

---

http://scholarship.law.marquette.edu/cgi/viewcontent.cgi?article=5348&context=mulr.

in unnecessary scrutiny by regulatory authorities;

3. Misunderstanding of addiction and dependence; and

4. Lack of understanding of regulatory policies and processes.[113]

261. While it acknowledges the risk of "abuse and diversion" (with little attention to addiction), the guide purports to offer "professional guidelines" that will "easily and efficiently" allow physicians to manage that risk and "minimize the potential for [such] abuse."[114] Indeed, it states that even for those patients assessed to have risk of substance abuse, "it does not mean that opioid use will become problematic or that opioids are contraindicated," just that physicians should use additional care in prescribing.

262. The guide further warns physicians to "[b]e aware of the distinction between pseudoaddiction and addiction" and teaches that behaviors such as "[r]equesting [drugs] by name," "[d]emanding or manipulative behavior," "[o]btaining opioid drugs from more than one physician" and "[h]oarding opioids," which are, in fact, signs of genuine addiction, are all really just signs of "pseudoaddiction."[115] It defines "Physical Dependence" as an acceptable result of opioid therapy not to be equated with addiction and states that while "[i]t may be tempting to assume that patients with chronic pain and a history of recreational drug use who are not adherent to a treatment regimen are abusing medications," there could be other acceptable reasons for non-adherence.[116] The guide, sponsored by the Manufacturing Defendants and their pain foundations, became the seminal authority on opioid prescribing for the medical profession and dramatically overstated the safety and efficacy of opioids and understated the risk of opioid addiction.

263. In 2012, Fishman updated the guide and continued emphasizing the "catastrophic" "under-treatment" of pain and the "crisis" such under-treatment created:

---

[113] Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide*, 8-9 (Waterford Life Sciences 2007).

[114] *Id.* at 9.

[115] *Id.* at 62.

[116] *Id.*

Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce diversion and misuse of prescription opioids, it's critical to remember that the problem of unrelieved pain remains as urgent as ever.[117]

264. The updated guide still assures that "[o]pioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and noncancer origins."[118]

265. In another guide by Fishman, he continues to downplay the risk of addiction: "I believe clinicians must be very careful with the label 'addict.' I draw a distinction between a 'chemical coper' and an addict."[119] The guide also continues to present symptoms of addiction as symptoms of "pseudoaddiction."

266. The heightened focus on the under-treatment of pain was a concept designed by Big Pharma to sell opioids. The FSMB actually issued a report calling on medical boards to punish doctors for inadequately treating pain.[120] Among the drafters of this policy was Dr. J. David Haddox ("Haddox"). He coined the term "pseudoaddiction," which wholly lacked scientific evidence but quickly became a common way for the Manufacturing Defendants and their allies to promote the use of opioids even to patients displaying addiction symptoms. Haddox later became a Purdue vice president who likened OxyContin to a vegetable, stating at a 2003 conference at Columbia University[121]: "'If I gave you a stalk of celery and you ate that, it would be healthy. But if you put it in a blender and tried to shoot it into your veins,

---

[117] Scott M. Fishman, *Responsible Opioid Prescribing: A Clinician's Guide* 10-11 (Waterford Life Sciences 2012).

[118] *Id.* at 11.

[119] Scott M. Fishman, *Listening to Pain: A Physician's Guide to Improving Pain Management Through Better Communication*, 45 (Oxford University Press 2012).

[120] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012, at A1.

[121] Gounder, Who Is Responsible, supra n. 101.

it would not be good.'"[122]

(f) The U.S. Senate Has Repeatedly Investigated RICO Marketing Participants' Relationships with Front Group

267. In 2012, and again in 2017, Front Groups' opioid-related treatment guides, as well as their funding sources, became the subject of a Senate investigation.

268. On June 8, 2012, the FSMB submitted a RICO letter to the U.S. Senate Finance Committee concerning its investigation into the abuse and misuse of opioids.[123] While the letter acknowledged the escalation of drug abuse and related deaths resulting from prescription painkillers, the FSMB continued to focus on the "serious and related problem" that "[m]illions of Americans suffer from debilitating pain – a condition that, for some, can be relieved through the use of opioids." Among other things, the letter stated, "[s]tudies have concluded that both acute pain and chronic pain are often under-treated in the United States, creating serious repercussions that include the loss of productivity and quality of life." The letter cited no such studies. The letter also confirmed that the FSMB's "Responsible Opioid Prescribing: A Physician's Guide" had been distributed in each of the 50 states and the District of Columbia.

269. Exposing the Financial Ties Between Opioid Manufacturers and Third Party Groups: A February 23, 2018 report, titled "Fueling an Epidemic Report Two: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups" and issued by the U.S. Senate Homeland Security & Government Affairs Committee, Ranking Member's Office, sheds additional light on the financial connections between opioid manufacturers and purportedly neutral patient advocacy organizations and medical professional societies that, unsurprisingly, have "echoed and amplified messages favorable to increased opioid use – and ultimately the financial interests of opioid manufacturers."[124]

---

[122] Keefe, Empire of Pain, supra n.8.

[123] June 8, 2012 Letter from Federation of State Medical Boards to U.S. Senators Max Baucus and Charles Grassley.

[124] *Id.* at 8-9.

270. The report details findings resulting from subpoenas issued by Senator McCaskill to five opioid manufacturers—Purdue, Janssen, Insys, Depomed and Mylan N.V. ("Mylan")—and to 15 purportedly neutral patient advocacy organizations and medical professional societies. "The information produced to the Committee demonstrates that many patient advocacy organizations and professional societies focusing on opioids policy have promoted messages and policies favorable to opioid use while receiving millions of dollars in payments from opioid manufacturers," the report found. It continued: "Through criticism of government prescribing guidelines, minimization of opioid addiction risk, and other efforts, ostensibly neutral advocacy organizations have often supported industry interests at the expense of their own constituencies."[125]

271. The five manufacturers whose information was subpoenaed by Senator McCaskill alone contributed almost $9 million combined to patient advocacy organizations and professional societies operating in the opioids policy area:

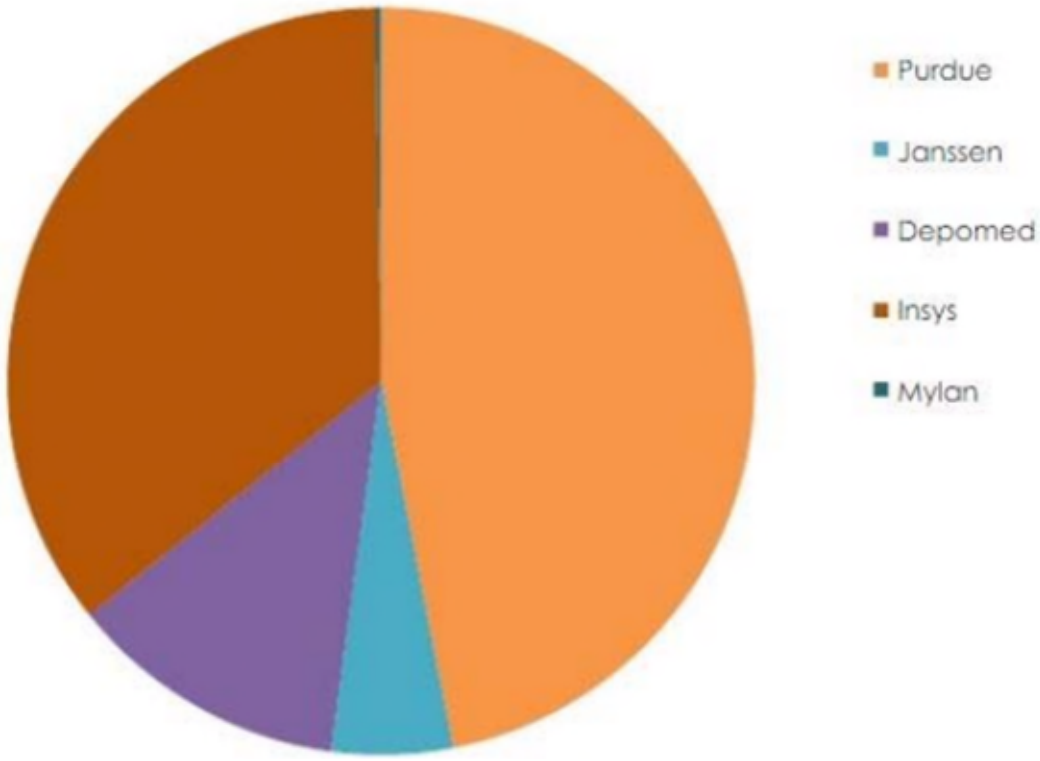
[125] *Id.* at 1.

FIGURE 1: Manufacturer Payments to Selected Groups, 2012-2017

	Purdue[22]	Janssen[23]	Depomed	Insys	Mylan	Total
Academy of Integrative Pain Management	$1,091,024.86	$128,000.00	$43,491.95	$3,050.00[24]	$0.00	$1,265,566.81
American Academy of Pain Medicine	$725,584.95	$83,975.00	$332,100.00	$57,750.00	$0.00	$1,199,409.95
AAPM Foundation	$0.00	$0.00	$304,605.00	$0.00	$0.00	$304,605.00
ACS Cancer Action Network	$168,500.00[25]	$0.00	$0.00	$0.00	$0.00	$168,500.00
American Chronic Pain Association	$312,470.00	$50,000.00	$54,670.00	$0.00	$0.00	$417,140.00
American Geriatrics Society	$11,785.00[26]	$0.00	$0.00	$0.00	$0.00	$11,785.00
American Pain Foundation	$25,000.00	$0.00	$0.00	$0.00	$0.00	$25,000.00
American Pain Society	$542,259.52	$88,500.00	$288,750.00	$22,965.00	$20,250.00	$962,724.52
American Society of Pain Educators	$30,000.00	$0.00	$0.00	$0.00	$0.00	$30,000.00
American Society of Pain Management Nursing	$242,535.00	$55,177.85[27]	$25,500.00[28]	$0.00	$0.00	$323,212.85
The Center for Practical Bioethics	$145,095.00	$18,000.00	$0.00	$0.00	$0.00	$163,095.00
The National Pain Foundation[29]	$0.00	$0.00	$0.00	$562,500.00	$0.00	$562,500.00
U.S. Pain Foundation	$359,300.00	$41,500.00	$22,000.00	$2,500,000.00[30]	$0.00	$2,922,800.00
Washington Legal Foundation	$500,000.00	$0.00	$0.00	$0.00	$0.00	$500,000.00
	$4,153,554.33	$465,152.85	$1,071,116.95	$3,146,265.00	$20,250.00	$8,856,339.13

272. As shown below, payments from Purdue comprise roughly half this funding, with Insys providing the second-largest amount.

FIGURE 2: Percentages of Total Payments by Manufacturer, 2012-2017



273. While Purdue's payments slowed starting in 2016, Insys' payments increased exponentially in 2017: societies' group executives, staff members, board members and advisory board members. When payments from all opioid manufacturers are tabulated, more than $10.6 million was paid to individuals affiliated with such organizations and societies from 2013 through the date of the report.

274. In addition to the nearly $9 million in payments to purportedly neutral patient advocacy organizations and medical professional societies, the five subpoenaed opioid manufacturers made an additional $1.6 million in payments to the organizations' and societies' group executives, staff members, board members and advisory board members. When payments from all opioid manufacturers are tabulated, more than $10.6 million was paid to individuals affiliated with such organizations and societies from 2013 through the date of the report:

FIGURE 8: Payments from All Opioid Manufacturers to Group-Affiliated Individuals, 2013-Present[52]

	Manufacturer Payments to Affiliated Individuals
The National Pain Foundation	$8,307,243.47
AAPM Foundation	$798,051.22
American Society of Pain Educators	$749,564.78
American Academy of Pain Medicine	$204,631.53
American Pain Society	$187,699.34
ACS Cancer Action Network	$154,578.09
American Chronic Pain Association	$145,861.30
Academy of Integrative Pain Management	$82,596.98
The Center for Practical Bioethics	$16,945.88
American Geriatrics Society	$7,548.35
U.S. Pain Foundation	$138.91
American Pain Foundation	N/A
American Society of Pain Management Nursing	N/A
Washington Legal Foundation	N/A
Total	$10,654,859.85

275. Included in the above-listed payments were payments of more than $140,000 from opioid manufacturers, including Endo, Purdue and Mallinckrodt, to ten members of the American Chronic Pain Association Advisory Board; $170,000 from Insys to National Pain Foundation ("NPF") chairman and founder D. Daniel Bennett; and more than $950,000 to members of the NPF Board of Directors from various opioid manufacturers, including more than $250,000 from Insys alone.

276. Worse still, the organizations provided limited disclosures of these sources of funding—when they provided any information at all. The American Society of Pain Educators, the NPF, and the Academy of Integrative Pain Management provided no information concerning their policies for disclosing donors or donations, while several others stated explicitly that they did not disclose any information concerning donor relationships. When the groups investigated did disclose their sources of funding, they did so without providing specifics as donation amounts.

277. Most importantly, many of the groups investigated "amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain." Several of the groups "also lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for overprescription and misbranding."[126] The report provided details regarding four ways the groups investigated set about these tasks.

278. First, the report states that "[m]any of the groups have issued guidelines to physicians and other health practitioners that minimize the risk of opioid addiction or emphasize the long-term use of opioids to treat chronic pain."[127] The report provides examples, including: (i) the AAPM's and APS's 1997 consensus statement endorsing opioids for chronic pain and stating that the risk of addiction was low; (ii) the 2009 issuance of guidelines by the AAPM and the APS allegedly promoting opioids as safe and effective for chronic pain and concluding the risk of addiction was manageable regardless of past abuse history; (iii) the 2009 issuance of guidelines by the American Geriatrics Society ("AGS") for the management of persistent pain recommending that opioids should be considered for all patients with moderate to severe pain in older patients and stating that the risks of addiction are exceedingly low in older patients; and (iv) the creation of a 2009 patient education guide by the AGS, the AAPM and Janssen stating that opioids are rarely addictive when used properly to manage chronic pain.

279. Second, the report notes that "[a]dvocacy groups have engaged in extensive lobbying efforts to either defeat legislation restricting opioid prescribing or promote laws encouraging opioid treatment with pain."[128] For example, in 2014 the Academy of Integrative Pain Management and the American Cancer Society Cancer Action Network led

[126] *Id.* at 12.

[127] *Id.*

[128] *Id.* at 13.

the effort to protect a law making it difficult to discipline doctors for overprescribing opioids and prohibited doctors from refusing to prescribe opioids unless they also referred the patient to an "opioid-friendly" doctor.

280. Third, the report criticized a majority of the groups for strongly criticizing CDC guidelines issued in 2016 providing prescribing recommendations for primary care doctors who are prescribing opioids for chronic pain outside of active treatment of cancer, palliative care and end-of life care. These guidelines were "'the first national standards for prescription painkillers'" and were "perhaps the first major step from the federal government [] toward limiting opioid prescriptions for chronic pain in the face of an unprecedented public health crisis."[129] However, most industry groups opposed the guidelines. For example, David Carr, the immediate past president of the AAPM, criticized the guidelines as reflecting "'disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence.'" Other groups complained that draft guidelines "were not transparent," cited purported conflicts of interest among those who created them, criticized the "'overly secretive manner'" in which they'd been developed, and called them "'inherently biased.'"[130]

281. Fourth, several of the advocacy groups and professional societies organized legal efforts to challenge government actions to punish executives responsible for fraudulent opioid marketing and doctors who overprescribed opioids. For example, the NPF submitted an amicus brief to the U.S. Court of Appeals for the Fourth Circuit in support of a doctor convicted of 16 counts of drug trafficking for prescribing massive quantities of oxycodone and other narcotics – in one instance, more than 1,600 per day – to patients in chronic pain. In its brief, the NPF opposed the conviction, criticizing the holding that "'a doctor acting in the good faith belief that he was serving the best medical interest of his patient could be found to be a drug dealer.'"[131] The Washington Legal Foundation filed an amicus brief in

[129] *Id.* at 13-14.

[130] *Id.* at 14.

[131] *Id.* at 15

the U.S. Court of Appeals for the District of Columbia Circuit arguing that the exclusion of three former Purdue executives from participation in federal healthcare programs for 12 years for their admitted failure to prevent fraudulent marketing of OxyContin raised "serious constitutional due process concerns."

282. In conclusion, the report found that, while health advocacy organizations are "'among the most influential and trusted stakeholders in U.S. health policy,'" the reality is that their "'positions closely correspond to the marketing aims of pharmaceutical and device companies,'" including in the area of opioids policy. "The findings in this report indicate that this tension exists in the area of opioids policy – that organizations receiving substantial funding from manufacturers have, in fact, amplified and reinforced messages favoring increased opioid use." This amplification "may have played a significant role in creating the necessary conditions for the U.S. opioids epidemic."[132]

G. Defendants Worked Together to Cause an Explosion in Opioid Prescribing, Use, Misuse, Abuse, and Addiction Through Their Deceptive Marketing Schemes and Unlawful and Unfair Business Practices, which has also Created and Proliferated a Public Nuisance

1. RICO Marketing Participants' Deceptive Marketing Scheme Has Caused and Continues to Cause a Huge Increase in Opioid Prescriptions and Use in Bullhead City

283. The RICO Marketing Participants' misrepresentations deceived and continue to deceive doctors in, and residents of, Bullhead City about the risks and benefits of long-term opioid use. Studies also reveal that some doctors and many patients are not aware of or do not understand these risks and benefits. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive. Indeed, Arizona residents in treatment for opioid

[132] *Id.* at 17.

addiction, including residents of Bullhead City, confirm that they were never told that they might become addicted to opioids when they started taking them, were told that they could easily stop using opioids, or were told that the opioids they were prescribed were less addictive than other opioids.

284. The RICO Marketing Participants knew and should have known that their misrepresentations about the risks and benefits of long-term opioid use were false and misleading when they made them.

285. The RICO Marketing Participants' deceptive marketing scheme and their unlawful and unfair business practices caused and continue to cause doctors and other clinicians in Bullhead City to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent the Manufacturer Defendants' deceptive marketing scheme and their unlawful and unfair business practices, these doctors would not have prescribed as many opioids to as many patients, and there would not have been as many opioids available for misuse and abuse or as much demand for those opioids.

286. The RICO Marketing Participants' deceptive marketing scheme and their unlawful and unfair business practices also caused and continue to cause patients in Arizona, including residents of Bullhead City, to purchase and use opioids for their chronic pain believing they are safe and effective. Absent Defendants' deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them. The Manufacturer Defendants' deceptive marketing and their unlawful and unfair business practices have caused and continue to cause the prescribing and use of opioids to explode in Bullhead City.

287. In Bullhead City, the RICO Marketing Participants' deceptive marketing of the abuse-deterrent properties of their opioids during the past few years has been particularly effective. For example, one survey reports that pain specialists were more likely to recognize that OxyContin had abuse deterrent properties and to prescribe OxyContin specifically because of those properties. Further, prescribers who knew of OxyContin's abuse deterrent properties were using more of it than those who did not know it was an AD opioid. Although

sales of AD opioids still represent only a small fraction of opioids sold (less than 5% of all opioids sold in 2015), they represent a disproportionate share of opioid sales revenue ($2.4 billion or approximately 25% in opioid sales revenue in 2015).

288. The dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in the Manufacturer Defendants' spending on their deceptive marketing scheme. The Manufacturer Defendants' spending on opioid marketing totaled approximately $91 million in 2000. By 2011, that spending had tripled to $288 million.

2. By Causing an Explosion in Opioid Prescriptions and Use, the RICO Marketing Participants Have Created and Maintained a Public Nuisance Affecting Health and Safety in Bullhead City

289. The escalating number of opioid prescriptions written by doctors who were deceived by the Manufacturer Defendants' deceptive marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the U.S. and Arizona, including in Bullhead City.

290. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."

291. In August 2016, U.S. Surgeon General Vivek Murthy published an open letter to be sent to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."

292. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving prescription opioids for chronic pain account for the majority

of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

293. Contrary to the Manufacturer Defendants' misrepresentations, most opioid addiction begins with legitimately prescribed opioids. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from pill mills, drug dealers or the internet. Numerous doctors and substance abuse counselors in Arizona note that many of their patients who misuse or abuse opioids started with legitimate prescriptions.

294. As the FDA observed in 2016, the opioid epidemic is getting worse, not better. The overprescribing of opioids for chronic pain caused by the Manufacturer Defendants' deceptive marketing scheme has also resulted in a dramatic rise in the number of infants in Arizona who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome. These infants face painful withdrawal and may suffer long-term neurologic and cognitive impacts.

295. The Manufacturer Defendants' creation, through false and misleading advertising and other unlawful and unfair conduct, of a virtually limitless opioid market has significantly harmed Bullhead City. The Manufacturer Defendants' success in extending the market for opioids to new patients and chronic pain conditions has created an abundance of drugs available for non-medical and criminal use and fueled a new wave of addiction and injury. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.

296. The rise in opioid addiction caused by the Manufacturer Defendants' deceptive marketing scheme has also resulted in an explosion in heroin use. Almost 80% of those who used heroin in the past year previously abused prescription opioids.

297. Many patients who become addicted to opioids will lose their jobs. Some will lose their homes and their families. Some will get treatment and fewer will successfully complete it; many of those patients will relapse, returning to opioids or some other drug. Of those who continue to take opioids, some will overdose—some fatally, some not. Others

will die prematurely from related causes—falling or getting into traffic accidents due to opioid-induced somnolence; dying in their sleep from opioid-induced respiratory depression; suffering assaults while engaging in illicit drug transactions; or dying from opioid-induced heart or neurological disease.

298. Absent each Manufacturer Defendants' deceptive marketing scheme and their unlawful and unfair business practices, the public health and safety crisis caused by opioid misuse, abuse, and addiction in Bullhead City, would have been averted or much less severe.

299. These harms in Bullhead City, caused by the Manufacturer Defendants' deceptive marketing schemes and unlawful and unfair business practices are a public nuisance because they are "injurious to health" and interfere "with the comfortable enjoyment of life" and "property," and because they "affect[] at the same time" "entire communit[ies]" and "neighborhoods" and "any considerable number of persons."[133]

3. RICO Marketing Participants Knew Their Deceptive Marketing Schemes Would Devastate Bullhead City by Creating Public Nuisance

300. The Manufacturer Defendants knew and should have known about these harms that their deceptive marketing and unlawful and unfair business practices have caused and continue to cause in Bullhead City. The Manufacturer Defendants closely monitored their sales and the habits of prescribing doctors. Their sales representatives, who visited doctors and attended CMEs, knew which doctors were receiving their messages and how they were responding. The Manufacturer Defendants also had access to and watched carefully government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. They knew—and, indeed, intended—that their misrepresentations would persuade doctors in Bullhead City to prescribe, and patients in Bullhead City to use, their opioids for chronic pain.

[133] A.R.S. 13-2917(A).

4. RICO Marketing Participants' Conduct and Role in Creating or Assisting in Creating a Public Nuisance Constitutes A "Pattern of Racketeering Activity," Which Is Not Excused by the Actions of Any Third Parties

301. The Manufacturer Defendants' actions are not permitted nor excused by the fact that their drug labels may have allowed or did not exclude the use of opioids for chronic pain. FDA approval of opioids for certain uses did not give the Manufacturer Defendants license to misrepresent the risks and benefits of opioids. Indeed, the Manufacturer Defendants' misrepresentations were directly contrary to pronouncements by and guidance from the FDA based on the medical evidence and their own labels.

302. Nor is the Manufacturer Defendants' causal role broken by the involvement of doctors. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source prescribers could rely on for information and prevented them from making informed treatment decisions. The Manufacturer Defendants also were able to harness and hijack what doctors wanted to believe—namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

303. Indeed, for the reasons stated above, it is clear that the RICO Marketing Participants, the Front Groups, and the KOLs were each willing participants in the Opioid Marketing Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose in the following ways:

a. Creating and providing a body of deceptive, misleading and unsupported medical and popular literature about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

b. Creating and providing a body of deceptive, misleading and unsupported electronic and print advertisements about opioids that (i) understated the risks and overstated

the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

c. Creating and providing a body of deceptive, misleading and unsupported sales and promotional training materials about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

d. Creating and providing a body of deceptive, misleading and unsupported CMEs and speaker presentations about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

e. Selecting, cultivating, promoting and paying KOLs based solely on their willingness to communicate and distribute the RICO Marketing Participants' messages about the use of opioids for chronic pain;

f. Providing substantial opportunities for KOLs to participate in research studies on topics the RICO Marketing Participants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

g. Paying KOLs to serve as consultants or on the RICO Marketing Participants' advisory boards, on the advisory boards and in leadership positions on Front Groups, and to give talks or present CMEs, typically over meals or at conferences;

h. Selecting, cultivating, promoting, creating and paying Front Groups based solely on their willingness to communicate and distribute the RICO Marketing Participants' messages about the use of opioids for chronic pain;

i. Providing substantial opportunities for Front Groups to participate in and/or publish research studies on topics the RICO Marketing Participants suggested or chose (and paid for), with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

j. Paying significant amounts of money to the leaders and individuals associated with Front Groups;

k. Donating to Front Groups to support talks or CMEs, that were typically presented over meals or at conferences;

l. Disseminating many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;

m. Sponsoring CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;

n. Developing and disseminating pro-opioid treatment guidelines with the help of the KOLs as authors and promoters, and the help of the Front Groups as publishers, and supporters;

o. Encouraging Front Groups to disseminate their pro-opioid messages to groups targeted by the RICO Marketing Participants, such as veterans and the elderly, and then funding that distribution;

p. Concealing their relationship to and control of Front Groups and KOLs from the Plaintiff and the public at large; and

q. Intending that Front Groups and KOLs would distribute through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain.

304. The hierarchical decision-making structure the RICO Marketing Participants implemented and controlled simply confirms their misconduct amounts to a common course of conduct, intended to increase the RICO Marketing Participants' sales from prescription opioids by encouraging the prescribing and use of opioids for chronic pain. The Opioid Marketing Enterprise likely involved thousands of separate instances of the use of the U.S. Mail or interstate wire facilities in furtherance of this enterprise, including eerily uniform misrepresentations, as well as concealments and material omissions regarding the beneficial

uses and non-addictive qualities for the long-term treatment of chronic, non-acute and non-cancer pain—all of which RICO Marketing Participants made to illegally increase their opioid sales by inducing consumers, prescribers, regulators and Plaintiff's reliance on their misrepresentations.

305. Each of these fraudulent mailings and interstate wire transmissions constitutes racketeering activity and collectively, these violations constitute a pattern of racketeering activity, through which the RICO Marketing Participants, the Front Groups and the KOLs defrauded and intended to defraud Montana consumers, the State, and other intended victims.

306. RICO Marketing Participants' scheme was—and, in many aspects, remains—a continuing course of conduct in Bullhead City.

H. RICO Marketing Participants' Fraudulent Marketing Has Led To Record Profits

307. While the use of opioids has taken an enormous toll on Bullhead City and its residents, the Manufacturer Defendants have realized blockbuster profits. In 2014 alone, opioids generated $11 billion in revenue for drug companies like the Manufacturer Defendants. Indeed, financial information indicates that each Manufacturer Defendant experienced a material increase in sales, revenue, and profits from the false and misleading advertising and other unlawful and unfair conduct described above.

I. The Sacklers Led Purdue's Misconduct

308. Arizona laws against both the creation of a public nuisance as well as the unfair and deceptive conduct in commerce applies to individuals regardless of whether they are officers, directors, or employees. Holding individuals personally liable for their misconduct does not require piercing a corporate veil. Individuals are personally liable if: (a) they participated in the misconduct; or (b) they knew about the misconduct and failed to stop it; or (c) they should have known about the misconduct and they failed to stop it.[134] In this

[134] *See* A.R.S. § 10-830.

case, the Individual Defendants made the decisions to break the law; they controlled the unfair and deceptive conduct; and they personally collected many millions of dollars from the deception.

309. Each individual defendant knowingly and intentionally sent sales representatives to promote opioids to prescribers in Arizona thousands of times.

310. Each individual defendant knew and intended that the sales reps in Arizona would unfairly and deceptively promote opioid sales that are risky for patients, including by:

- falsely blaming the dangers of opioids on patients instead of the addictive drugs;
- pushing opioids for elderly patients, without disclosing the higher risks;
- pushing opioids for patients who had never taken them before, without disclosing the higher risks;
- pushing opioids as substitutes for safer medications, with improper comparative claims;
- falsely assuring doctors and patients that reformulated OxyContin was safe;
- pushing doctors and patients to use higher doses of opioids, without disclosing the higher risks;
- pushing doctors and patients to use opioids for longer periods of time, without disclosing the higher risks; and
- pushing opioid prescriptions by doctors that Purdue knew were writing dangerous prescriptions.

311. Each individual defendant knew and intended that the sales representatives would not tell doctors and patients in Arizona and Bullhead City about the truth about Purdue's opioids. Indeed, they knew and intended these unfair and deceptive tactics achieved their purpose by concealing the truth.

312. Each individual defendant knew and intended that prescribers, pharmacists, and patients in Arizona would rely on Purdue's deceptive sales campaign to prescribe, dispense, and take Purdue opioids. Securing that reliance was the purpose of the sales campaign.

313. Each individual defendant knew and intended that staff reporting to them

would pay top prescribers tens of thousands of dollars to encourage other doctors to write dangerous prescriptions across the State of Arizona as well as in Bullhead City.

314. Each individual defendant knew and intended that staff reporting to them would reinforce these misleading acts through thousands of additional acts in Bullhead City including by sending deceptive publications to Plaintiff's local doctors and deceptively promoting Purdue opioids at Plaintiff's local healthcare facilities and other institutions.

315. Each individual defendant knew and intended that staff reporting to them would reinforce these misleading acts through thousands of additional acts in Arizona, including by sending deceptive publications to Arizona doctors and deceptively promoting Purdue's opioids in Bullhead City.

316. Each individual defendant knowingly and intentionally took money from Purdue's deceptive business in Arizona.

317. Each individual defendant knowingly and intentionally sought to conceal his or her misconduct.

1. Richard Sackler, Beverly Sackler, David Sackler, Ilene Sackler Lefcourt, Jonathan Sackler, Kathe Sackler, Mortimer Sackler, and Theresa Sackler

318. The opioid epidemic can be largely traced back to eight people in a single family—the Sacklers—who made decisions for their own pecuniary benefit that caused much of the opioid epidemic. The Sackler family owns Purdue, and have always held a majority of the seats on its Board. They controlled their own privately held drug company, and as a result, the Sacklers had the power to decide how their addictive narcotics were sold. They hired hundreds of workers to carry out their plan, and they fired those who failed to sell enough drugs. They got more patients on opioids, at higher doses, and for longer, than ever before. And to reward themselves, they paid themselves billions of dollars. They are responsible for addiction, overdose, and death that damaged millions of lives. They should be held accountable now.

2. The Sacklers' Misconduct Leading To The 2007 Judgment

319. The misconduct of Richard, Beverly, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler was neither new, nor accidental. Indeed, it was particularly unfair, deceptive, unreasonable, and unlawful because they already had been given a second chance. From the 1990s until 2007, they presided over a decade of illegal and immoral conduct, which led to criminal convictions, a judgment of this Court, and commitments that Purdue would not deceive doctors and patients again. That background confirms that their subsequent and sustained misconduct was knowing and intentional.

320. Purdue Frederick Company, the Sacklers' first drug company, was purchased by them in 1952. In 1990, they created Purdue Pharma Inc. and Purdue Pharma L.P. Richard, Beverly, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler took seats on the Board.[135] For events before July 2012, this Amended Complaint uses "the Sacklers" to refer to them. David Sackler joined the Board in July 2012. From that time forward, "the Sacklers" includes him as well.

321. The Sacklers insisted that the family control Purdue at all times. From 1990 until today, the family has consistently held the majority of seats on the Board. In 1994, Jonathan Sackler issued a memorandum to Purdue staff requiring that the Sacklers should receive "all Quarterly Reports and any other reports directed to the Board."

322. Purdue launched OxyContin in 1996. It quickly earned the superlative "honor" of becoming one of the deadliest drugs of all time. The FDA scientist, Curtis Wright, who evaluated OxyContin wrote in his original review: "Care should be taken to limit competitive promotion."[136] The Sacklers disagreed.

---

[135] Purdue Pharma Inc.'s 1991 filings with the Secretary of State of Connecticut state that it was incorporated in New York on October 2, 1990. Richard, Ilene, Jonathan, and Kathe Sackler are all listed as directors on the earliest (1991) report. Beverly, Mortimer, and Theresa all appear on the 1995 report. (*See* The Office of Secretary of State Denise W. Merill, https://www.concord-sots.ct.gov/CONCORD/online?sn=PublicInquiry&eid=9740.)

[136] Curtis Wright, ultimately approved OxyContin for wide use. Shortly after approval, he left the FDA, joining Purdue within two years of his departure.

323. The Sacklers were—and have always been—behind Purdue's decision to deceive doctors and patients about the risks and benefits of Purdue's opioids. In 1997, Richard Sackler, Kathe Sackler, and other Purdue executives determined that doctors had the beneficial but crucial misconception that OxyContin was weaker than morphine, which led them to prescribe OxyContin much more often, even as a substitute for Tylenol. The truth was that OxyContin is more potent than morphine. Richard directed Purdue staff not to tell doctors the truth, because the truth would reduce OxyContin sales.

324. In 1999, Richard Sackler became the President of Purdue. Jonathan, Kathe, and Mortimer were Vice Presidents. The company hired hundreds of sales representatives and taught them all the false claims they would need to sell drugs. Purdue managers tested the sales representatives on the most important false statements during training at company headquarters. On the crucial issue of addiction, which would destroy so many lives, Purdue trained its sales representatives to deceive doctors by insisting that the risk of addiction was "less than one percent."[137]

325. In February of 2001, a federal prosecutor reported 59 deaths from OxyContin in a single state.

326. Meanwhile, Richard Sackler came up with Purdue's plan to blame and stigmatize people who become addicted to opioids. Sackler wrote, "We have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals."

327. The Sacklers delighted in their success by landing on the front page of the *New York Times* which reported that "OxyContin's sales have hit $1 billion, more than even Viagra's." The only dark spot? The article reported that "OxyContin has been a factor in the deaths of at least 120 people, and medical examiners are still counting."[138]

---

[137] Barry Meier, *Pain Killer* (1 ed. 2003) at 99.

[138] Meier, Barry, *Sales of Painkiller Grew Rapidly, But Success Brought a High Cost* (March 5, 2001) https://www.nytimes.com/2001/03/05/business/sales-of-painkiller-grew-rapidly-but-success-brought-a-high-cost.html

328. When *Time* magazine published an article about OxyContin deaths, Purdue employees told Richard Sackler they were worried. Richard responded with his thematic message to the staff: *Time*'s coverage of people who lost their lives to OxyContin was not "balanced," and the deaths were the fault of "the drug addicts," instead of Purdue. "We intend to stay the course and speak out for people in pain—who far outnumber the drug addicts abusing our product."

329. Meanwhile, Purdue kept pushing opioids and people kept dying. Soon, the company was engulfed in a wave of investigations by state attorneys general, the DEA, and the U.S. Department of Justice. In 2003, Richard Sackler left his position as President of Purdue. After a few more years of investigation, Jonathan, Kathe, and Mortimer Sackler resigned from their positions as Vice Presidents. But those resignations were superficial. The Sacklers remained in control of the company. They still owned Purdue. They still controlled the Board. They still paid themselves the profits. And they continued to direct Purdue's deceptive marketing campaign.

330. By 2006, prosecutors found damning evidence that Purdue intentionally deceived doctors and patients about its opioids.[139] In May 2007, The Purdue Frederick Company confessed to a felony and effectively went out of business. However, the Sacklers continued their opioid business in two other companies: Purdue Pharma Inc. and Purdue Pharma L.P.

331. The Sacklers voted to admit in an Agreed Statement of Facts that, for more than six years, supervisors and employees *intentionally* used to deceive doctors about OxyContin: "Beginning on or about December 12, 1995, and continuing until on or about June 30, 2000, certain Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and

[139] U.S. Department of Justice, *Statement of U.S. Attorney John Brownlee on the Guilty Plea of the Purdue Frederick Company and Its Executes for Illegally Misbranding OxyContin* (Oct. 25, 2006), https://www.ctnewsjunkie.com/upload/2016/02/usdoj-purdue-guilty-plea-5-10-2007.pdf

diversion, and less likely to cause tolerance and withdrawal than other pain medications."[140]

332. The Sacklers entered into a plea agreement that stated: "Purdue is pleading guilty as described above because Purdue is in fact guilty."[141] Those intentional violations of the law happened while Richard Sackler was President; Jonathan, Kathe, and Mortimer were Vice Presidents; and Richard, Jonathan, Kathe, Mortimer, Ilene, Beverly, and Theresa Sackler were all on the Board.

333. The Sacklers also voted for Purdue to enter a Corporate Integrity Agreement with the U.S. government. The agreement required the Sacklers to ensure that Purdue did not deceive doctors and patients again. As part of the agreement, the family promised to comply with rules that prohibit deception about Purdue opioids. They were required to complete hours of training to ensure that they understood the rules. They were required to report any deception. Richard, Beverly, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler each certified in writing to the government that he or she had read and understood the rules and would obey them.[142]

334. Finally, the Sacklers voted to enter into a Consent Judgment in this Court ("2007 Judgment"). The 2007 Judgment ordered that Purdue "shall not make any written or oral claim that is false, misleading, or deceptive" in the promotion or marketing of OxyContin. The judgment further required that Purdue provide balance regarding risks and benefits in all promotion of OxyContin. That judgment required balance in presentation of the risks of taking higher doses for longer periods and the risks of addiction, overdose, and death.[143]

---

[140] *See, e.g.*, Attachment B to Plea Agreement in *United States v. The Purdue Frederick Co., Inc.*, Case No. 1:07-cr-00029-JPJ: Purdue Agreed Statement of Facts, ("PASF") at ¶20.

[141] 2007-05-09 Plea Agreement. https://www.ctnewsjunkie.com/upload/2016/02/usdoj-purdue-guilty-plea-5-10-2007.pdf

[142] 2007-05-09 Plea Agreement. https://www.ctnewsjunkie.com/upload/2016/02/usdoj-purdue-guilty-plea-5-10-2007.pdf

[143] 2007-05-15 Consent Judgment, *Commonwealth v. Purdue Pharma L.P. et al.*, No. 07-1967(B), Mass. Super. Ct.

335. The 2007 Judgment also required that Purdue establish and follow an abuse and diversion detection program to identify high-prescribing doctors who show signs of inappropriate prescribing, stop promoting drugs to them, and report them to the authorities:

> "Upon identification of potential abuse or diversion," Purdue must conduct an inquiry and take appropriate action, "which may include ceasing to promote Purdue products to the particular Health Care Professional, providing further education to the Health Care Professional about appropriate use of opioids, or providing notice of such potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities."[144]

336. The 2007 Judgment and related agreements should have ended the Sacklers' misconduct for good. Instead, the Sacklers decided to expand their deceptive sales campaign to make more money from more patients on more dangerous doses of opioids.

3. The Sacklers Continue Their Misconduct From The 2007 Judgment

337. From the 2007 Judgment to 2018, the Sackler family controlled Purdue's deceptive sales campaign. They directed the company to hire hundreds more sales representatives to visit doctors thousands more times than they otherwise could. They insisted that sales representatives repeatedly visit the most prolific prescribers. They directed representatives to encourage doctors to prescribe more of the highest doses of opioids. They studied and adopted unlawful tactics to keep patients on opioids longer and then ordered staff to use them. They asked for detailed reports about doctors suspected of misconduct, how much money Purdue made from them, and how few of them Purdue had reported to the authorities. The family was well informed: They sometimes demanded more detail than anyone else in the entire company, so staff had to create special reports just for them. Richard Sackler even went into the field to promote opioids to doctors and supervise representatives face-to-face.

338. The Sacklers' iron rule impacted everyone in the company from the top down. When they berated sales managers, the managers turned around and passed angry messages

---

144 *Id.*

to the sales representatives in the field. When Richard Sackler complained to sales managers, sales managers threatened their sales representatives with termination.

339. In July 2007, staff informed the Sacklers that more than 5,000 cases of "adverse events" had been reported to Purdue in just the first three months of 2007. Staff also told the Sacklers that Purdue received 572 "Reports of Concern" about abuse and diversion of Purdue opioids during Q2 2007. Shockingly, staff reported to the Sacklers that they completed only 21 field inquiries in response to these reports. Staff also told the Sacklers that they received more than 100 calls to Purdue's compliance hotline during the quarter, which was a "significant increase," but Purdue did not report any of the hotline calls or Reports of Concern to the FDA, DEA, Department of Justice, or state authorities.

340. Purdue's intentional failure to report abuse and diversion continued unabated, even though the 2007 Judgment required Purdue to report "potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities." Instead of reporting dangerous prescribers, or even directing sales representatives to stop visiting them, the Sacklers kept pushing opioids to whoever prescribed them the most.

341. The Sacklers were further aware that Purdue staff members continued to mail out thousands of deceptive marketing materials. The single most-distributed material was volume #1 of Purdue's "*Focused and Customized Education Topic Selections in Pain Management*" ("FACETS"). In FACETS, Purdue falsely instructed doctors and patients that physical dependence on opioids is not dangerous and instead improves patients' "quality of life." In the same material, Purdue also falsely told doctors and patients that signs of addiction are actually "pseudoaddiction," and that doctors should respond by prescribing more opioids. Staff told the Sacklers that another of the publications they had sent most often to doctors was "*Complexities in Caring for People in Pain*." In it, Purdue again reiterated its false claim that warning signs of addiction are really "pseudoaddiction" that should be with more opioids.

342. At the same time, Purdue was making more money than expected. A few months earlier, there had been a projected a profit of $407,000,000; now it expected more

than $600,000,000. The Sacklers had every reason to know that Purdue employed 301 sales representatives to promote opioids and that sales representatives were the largest group of Purdue employees by far. In comparison, Purdue employed only 34 people in drug discovery.

343. As a result of Purdue's overwhelming number of sales representatives—which varied from a low of 300 reps in mid-2007 to a peak of over 700 representatives in 2015—the impact of Purdue on Arizona and Bullhead City was significant and direct—from the 2007 felony conviction to 2018, Purdue sales representatives visited Plaintiff's local prescribers regularly.

344. In August of 2007, Howard Udell was serving as Purdue's top lawyer, even after his 2007 criminal conviction for assisting Purdue in misleading doctors and patients by claiming that OxyContin was less prone to abuse than similar drugs. He warned the Sacklers about the negative press OxyContin was receiving.

345. In October of 2007, the Sacklers learned that Purdue received 284 Reports of Concern about abuse and diversion of Purdue's opioids in Q3 2007, and they conducted only 46 field inquiries in response. Moreover, they received 39 tips to Purdue's compliance hotline during the quarter, but Purdue did not report any of them to the authorities.

346. By late 2007, Purdue expected to collect more than half its total revenue from sales of 80mg OxyContin—its most powerful, most profitable, and most addictive pill.

347. In January 2008, the Sacklers had every reason to know that Purdue still employed 304 sales representatives and they were succeeding at the goal of promoting higher doses of opioids. Purdue's net sales were just over $1 billion in 2007, almost double what the company had projected. OxyContin accounted for more than 90% of those sales.

348. Purdue received 689 Reports of Concern about abuse and diversion of Purdue's opioids in Q4 2007, and they conducted only 21 field inquiries in response. Purdue received 83 tips to Purdue's compliance hotline during the quarter, but Purdue did not report any of them to the authorities. The Sacklers did nothing to comply with their obligations.

349. Instead of complying with their legal obligations, the Sacklers wanted more

details on tactics for pushing sales, including the distribution and use of savings cards for Purdue opioids.

350. The Sacklers made it a point to become personally involved in various decision-making process of the company, ranging from selling opioids door-to-door and arranging in-person visits to doctor's offices and hospitals, to pressuring Purdue's sales forces to increase orders—whatever the cost.

351. The Sacklers also ensured that their top-performing sales representatives were rewarded. For example, top sales representatives were rewarded with bonuses and lavish, all-expense-paid vacations to tropical islands, hoping all the while that Purdue's relatively less productive sales representatives would hone in on the perks of increasing their sales, and ignore the clear risks of pushing higher doses of Purdue's opioids on vulnerable patients.

352. By 2008, Purdue was working on a crush-proof reformulation of OxyContin to extend Purdue's patent monopoly. The Sacklers learned that another company was planning clinical research to test whether crush-proof opioids were actually safer for patients. The Sacklers decided not to do the research because they wanted the profits from a new product—even if the deaths continued.

353. In March of 2008, Richard Sackler focused on Purdue's strategy for selling more OxyContin. In response to clear indications that Purdue's VP of Sales, Russell Gasdia, had doubts about the company's increasingly aggressive sales tactics, Richard Sackler immediately ramped up the pressure, both pushing staff to sell more of the highest doses of opioids and get more pills in each prescription, as well as seeking to identify tactics for exceeding prior sales numbers. Under Sackler's direction, Purdue began preparing plans for how adding sales representatives, opioid savings cards, and promoting more intermediate doses of OxyContin could help increase sales.

354. Staff told these Sacklers that they would use opioid savings cards to meet the challenge of keeping OxyContin scripts at the same level in 2008 as in 2007.

355. In April of 2008, staff told the Sacklers that Purdue employed 304 sales representatives and that the representatives had obtained data showing which pharmacies

stocked higher strengths of OxyContin, which helped them convince area doctors to prescribe the highest doses. At that time, the Sacklers learned that Purdue received 853 Reports of Concern about abuse and diversion of Purdue opioids in Q1 2008, and they had conducted only 17 field inquiries in response. Staff also reported to the Sacklers that they received 83 tips to Purdue's compliance hotline during the quarter, but did not report any of them to the authorities.

356. On April 18, 2008, Richard Sackler felt it was important to install a CEO who would be loyal to the family. He recommended John Stewart the position because of his loyalty. Richard also proposed that the family should either sell Purdue in 2008 or, if they could not find a buyer, milk the profits out of the business and "distribute more free cash flow" to themselves.

357. When the Sacklers directed Purdue to pay their family, they knew and intended that they were paying themselves from opioid sales in Arizona. Purdue and the Sacklers tracked revenue and staff reported to the Sacklers that prescriptions of Purdue's highest doses provided seven-figure revenues per year and represented a significant percentage of Purdue's overall revenues from high-dose opioids.

358. In May of 2008, the Sacklers received more ideas from Purdue staff about ways to promote Purdue's opioids. One strategy that particularly pleased the Sacklers was to deflect blame from Purdue's addictive drugs by stigmatizing people who become addicted. "KEY MESSAGES THAT WORK" included this dangerous lie: "It's not addiction, it's abuse. It's about personal responsibility." This blame-the-victim approach has characterized the Sacklers' response to the opioid crisis they helped create.

359. Meanwhile, Richard Sackler pushed Purdue's opioid savings cards. 67,951 patients had used Purdue's opioid savings cards, and that the cards provided a discount on a patient's first five prescriptions. Predictably, after five prescriptions, many patients would face significant withdrawal symptoms if they tried to stop taking opioids. 27% of patients (more than 18,000 people) had used the cards for all five prescriptions.

360. In July of 2008, Purdue's Fleet Department reported to the Sacklers that

Purdue had bought one hundred new Pontiac Vibes for the expanded sales force. Staff also told the Sacklers that Purdue received 890 Reports of Concern regarding abuse and diversion of Purdue's opioids in Q2 2008 and had conducted only 25 field inquiries in response. Staff reported to the Sacklers that they received 93 tips to Purdue's compliance hotline during the quarter, but did not report any of them to the authorities.

361. Staff also told the Sacklers that they promoted Purdue's opioids in various presentations, which echoed the company's messaging from presentations such as "*The Assessment and Management of Chronic Pain with an Emphasis on the Appropriate Use of Opioid Analgesics*" and "*The Role of Urine Drug and other Biofluid Assays in Pain Management.*" Through these presentations, the Sacklers intentionally ensured that a dangerous (and false) message would be disseminated to Arizona doctors and elsewhere—*i.e.*, Purdue's opioids were the best way to manage chronic pain and that urine tests protected patients from addiction were both part of Purdue's unfair and deceptive scheme.

362. In October of 2008, surveillance data monitored by Purdue indicated a "wide geographic dispersion" of abuse and diversion of OxyContin "throughout the United States." The Sacklers learned that "availability of the product" and "prescribing practices" were key factors driving abuse and diversion of OxyContin. On the same day, Purdue had begun a new "Toppers Club sales contest" for sales representatives to win bonuses, based on how much a representative increased OxyContin use in her territory and how much the representative increased the broader prescribing of opioids—the same "availability of product" and "prescribing practices" factors that worsen the risk of diversion and abuse. Purdue also knew it received 163 tips to Purdue's compliance hotline during Q3 2008, but did not report any of them to the authorities.

363. To the contrary, the Sacklers' decided to expand Purdue's sales forces, which effectively increased both the number of in-person visits to Arizona prescribers, as well as the disastrous consequences that would follow.

364. The Sacklers wanted to hire a new staff member who would contact prescribers electronically and would promote Purdue opioids through the deceptive website

Partners Against Pain.

365. Purdue received 122 tips to Purdue's compliance hotline during the first quarter of 2009, one of which was from an outside monitor. The Sacklers did nothing to stop the compliance problems, including the improper use of OxyContin marketing materials and opioid savings cards.

366. In addition to disregarding non-compliance, the Sacklers further instructed Purdue management to disregard supervision requirements under federal law mandating that—in order to mitigate the high risk of misconduct by sales representatives—Purdue managers needed to supervise sales representatives in-person at least five days each year.[145]

367. Still, the Sacklers and Purdue created new sales territories and expanded sales staff. The expansion was focused on the most prolific opioid prescribers, because "there are a significant number of the top prescribers" that Purdue had not been able to visit with its smaller force of sales reps.

368. By July of 2009, Purdue employed 429 sales reps. Richard Sackler was not satisfied with that number, wanting more.

369. By August of 2009, the 80mg OxyContin pill was far-and-away Purdue's best performing drug. Purdue sold many more kilograms of active ingredient in the 80mg dose than any other dose (about 1,000 kilograms: literally a ton of oxycodone).

370. Purdue and the Sacklers reviewed their newest OxyContin sales campaign, with the slogan: *Options*. The *Options* campaign exemplified the strategy that Purdue would follow for years to come—pushing doctors and patients up the ladder to higher doses. To make it easy for sales representatives to promote higher doses, suggesting that doctors could or should adjust the patient's dose as frequently as every one-to-two days. They planned to advertise the *Options* campaign in medical journals reaching 245,000 doctors.

371. By 2009, more than 160,000 patients had used Purdue's opioid savings cards, more than doubling the result reported to the Sacklers the summer before. Purdue and the

[145] Purdue Corporate Integrity Agreement section III.K., p. 23-24 (May 8, 2007), http://www.pharmacomplianceforum.org/docs/resources/PurdueCIA.pdf

Sacklers also decided to advertise OxyContin using a special television network and that thousands of doctors would be given free digital video recorders for their home televisions, in exchange for watching advertisements for drugs.

372. As set forth throughout this Complaint, the Sackler Defendants paved the way for the opioid epidemic in Bullhead City by organizing and ensuring the execution of an intentional, underhanded strategy to combine strong-arm sales tactics with misrepresentation about the benefits and risks of Purdue's opioids. The Sacklers accomplished their goal through not only their individual and combined actions, but also through the actions of their executive-agents, including Peter Boer, Judith Lewent, Cecil Pickett, Paulo Costa, Ralph Snyderman, John Stewart, Russel Gasdia, Mark Timney and Craig Landau. And they did so while making themselves extraordinarily wealthy. Ultimately, a single family, the Sacklers, drove much of the opioid epidemic, at the expense of Bullhead City, Arizona, as well as the entire nation.

J. John Kapoor and Michael Babich Led Insys's Misconduct

373. John Kapoor ("Kapoor"), the founder and majority owner of Insys, and Michael Babich ("Babich"), the former CEO and President of Insys, led a nationwide conspiracy to profit using bribes and fraud to cause the illegal distribution of Subsys.

374. Kapoor and Babich conspired to bribe practitioners in various states, including in Arizona, many of whom operated pain clinics, in order to get them to prescribe Subsys. In exchange for bribes and kickbacks, the practitioners wrote large numbers of prescriptions for patients, many of whom were not diagnosed with cancer, and therefore did not need Subsys.

375. Kapoor and Babich also conspired to mislead and defraud health insurance providers who were reluctant to approve payment for the drug when it was prescribed for non-cancer patients. They achieved this goal by setting up a "reimbursement unit" which was dedicated to obtaining prior authorization directly from insurers and pharmacy benefit managers.

376. Kapoor and Babich fueled the opioid epidemic by paying doctors to needlessly

prescribe Subsys for patients who did not need it, and without complying with Arizona law, thus putting patients at risk and contributing to the current opioid crisis. Kapoor and Babich committed fraud, placing profit before patient safety, to sell a highly potent and addictive opioid.

377. Indeed, in January of 2019 Defendant Babich pleaded guilty to charges of RICO conspiracy, conspiracy to commit wire fraud and conspiracy to violate the Anti-Kickback law[146]; further, on May 2, 2019, Defendant Kapoor was found guilty of racketeering conspiracy and running a nationwide bribery scheme.[147]

K. McKinsey & Co. Knowingly and Substantially Enabled and Conspired with the RICO Marketing Participants

1. McKinsey Was An Architect of the Opioid Marketing Participants' Deceptive Marketing Campaign

378. Unnamed co-conspirator McKinsey & Co. ("McKinsey") is one of the world's largest consulting companies, advising companies and governments all over the world and across diverse industries. McKinsey's vast influence sells itself on the notion that it can take whatever a company or government is doing, and help them do it better—including the promotion and sale of prescription opioids.

379. At all relevant times, McKinsey was as a consultant to the opioid industry.[148] As recently made public in connection with the Purdue Pharma, LP bankruptcy proceedings, McKinsey was the "primary architect"[149] of the deceptive opioid marketing campaigns that,

---

[146] J. Saltzman, *Former CEO says Insys founder pushed for higher doses of opioid*, BOSTON GLOBE (Feb. 12, 2019), https://www2.bostonglobe.com/business/2019/02/12/former-ceo-says-insys-founder-pushed-for-higher-doses-opioid/aZhLcDEnayOO3dzPlFn9gN/story.html

[147] G. Emanuel, *Opioid Executive John Kapoor Found Guilty in Landmark Bribery Case*, NPR (May 2, 2019) https://www.npr.org/2019/05/02/711346081/opioid-executive-john-kapoor-found-guilty-in-landmark-bribery-case

[148] Jef Feeley, *McKinsey Targeted by School Districts Over Opioid-Related Costs*, Bloomberg (May 6, 2021), available at https://www.bloomberg.com/news/articles/2021-05-06/mckinsey-targeted-by-school-districts-over-opioid-related-costs.

[149] KHN Morning Briefing, McKinsey's, Publicis' Roles In Opioid Epidemic Targeted By

as discussed herein, "turbocharged"[150] prescription opioid sales at a time when opioid abuse had already killed hundreds of thousands of Americans across the country—including in Bullhead City.[151]

380. For over a decade (at least), McKinsey has devised various promotional strategies and sales tactics for opioid manufacturers and distributors, helping them find ways to sell more opioids for the long-term treatment of chronic pain. McKinsey's clientele includes titans of the opioid industry, such as Manufacturer Defendants J&J, Endo, Teva and Par, as well as Distributor Defendant McKesson and the now-bankrupt manufacturer of OxyContin, Purdue Pharma, LP .[152]

381. In working with Purdue Pharma from 2004-2019, for instance, McKinsey developed several strategies for Purdue that successfully increased OxyContin sales to an unprecedented level. Indeed, early in their relationship, McKinsey advised Purdue that it could increase Oxycontin sales through physician targeting and specific messaging to prescribers, namely by exaggerating the safety and efficacy of prescription opioids for treating chronic pain, while downplaying the significant, concomitant risks of addiction, overdose and death. McKinsey's strategies would eventually become pillars of the Manufacturer Defendants' sales tactics for the next fifteen years.

382. Even worse, while McKinsey was encouraging Purdue and the Manufacturer

---

Lawsuits (May 7, 2021), available at https://khn.org/morning-breakout/mckinseys-publicis-roles-in-opioid-epidemic-targeted-by-lawsuits/.

[150] Gretchen Morgenson, *Consulting giant McKinsey allegedly fed the opioid crisis. Now an affiliate may profit from treating addicts*, NBC News (Feb. 8, 2021), available at https://www.nbcnews.com/news/us-news/consulting-giant-mckinsey-allegedly-fed-opioid-crisis-now-affiliate-may-n1256969.

[151] Luke Savage, *How McKinsey, the World's Most Elite Consulting Firm, Helped Turbocharge America's Opioid Epidemic*, Jacobin Magazine (Dec. 13, 2020), available at https://jacobinmag.com/2020/12/mckinsey-consulting-firm-opioid-epidemic-purdue-pharma.

[152] Jef Feeley, *McKinsey Opioid Work Included Advising Distributors, Tribe Says*, CLAIMS JOURNAL (June 4, 2021), available at https://www.claimsjournal.com/news/national/2021/06/04/304119.htm

Defendants to continue promoting their drugs in a way that significantly increased the prevalence of opioid addiction and death, McKinsey—through its subsidiary, IMO Partners—held substantial investments in opioid addiction centers and manufacturers of opioid rescue medications. As McKinsey knew at all relevant times, the demand for these companies would only increase if the number of opioid addicts and overdoses went up. For this reason, McKinsey knew it could make more money if the epidemic worsened, and it relentlessly pursued this strategy in an effort to profit from the national health crisis resulting from McKinsey's continuing violations of law.

383. McKinsey routinely encouraged its clients, including the Manufacturer Defendants and the Distributor Defendants, to utilize the promotional strategies McKinsey successfully designed for Purdue—the same illegal strategies that ultimately led to Purdue's felony misbranding conviction in 2007. As McKinsey knew, in connection with that conviction, three of Purdue's former executives pleaded guilty to illegally promoting Oxycontin and misleading the public about the risks and benefits of the drug.[153] Despite this knowledge, McKinsey did not withdraw from its business relationship with Purdue, and instead continued to advise and encourage the Oxycontin manufacturer to utilize McKinsey's aggressive and deceptive promotional strategies for approximately nine more years, through 2019.

384. In 2008, for example—just one year after Purdue's criminal conviction—McKinsey worked with Purdue to develop its FDA mandated risk evaluation and mitigation strategy ("REMS"). McKinsey advised Purdue to "band together" with other opioid manufacturers toward a class REMS to "formulate arguments to defend against strict treatment by the FDA." Ultimately, the FDA adopted a class-wide REMS that resulted in highdose OxyContin remaining subject to the same oversight as lower dose opioids.

---

[153] *United States v. Purdue Frederick Co. et al.*, No 1:07-CR-00029, Western District of Virginia; *see also* Sue Linsey, *Oxycontin Maker, Execs Guilty of Deceit*, Associated Press, USA TODAY (May 11, 2007), available at http://usatoday30.usatoday.com/money/economy/2007-05-10-1771944037_x.htm.

385. Again, in 2009, Purdue hired McKinsey to increase "brand loyalty" to Oxycontin. McKinsey, unphased by the epidemic of addiction and death it was contributing to, helped Purdue identify the best ways to ensure loyalty to the brand, including the following tactics noted above: (i) targeting opioid naïve patients; and (ii) disseminate misleading targeted messaging to specific prescribers, in an effort to convince them to prescribe more opioids. Purdue, in turn, adopted McKinsey's proposed strategies prescriber messaging and incorporated them into Purdue's marketing and sales campaigns.

386. Moreover, McKinsey actively encouraged Purdue to skirt their regulatory obligations. Indeed, when a large pharmacy chain took steps to scrutinize suspicious opioid orders, McKinsey stressed to Purdue's owners the "need to take action" on this "urgent" issue affecting OxyContin. Instead of urging Purdue to refrain from selling suspicious amounts and/or dosages of opioids, McKinsey told Purdue's owners to engage in senior level discussions with the pharmacy chain, increase efforts with patient advocacy groups to clamor against dispensing limits, and accelerate considerations of an alternative distribution channel, such as delivering OxyContin directly to patients through mail-order pharmacies.

387. Thereafter, McKinsey continued to work with Purdue, including on a project that identified the growing addiction crisis as a profit-making opportunity. McKinsey told Purdue that it should strive to become a provider across the spectrum of drug abuse and addiction, given the opportunities this would create for Purdue. McKinsey advised Purdue to start manufacturing and marketing opioid rescue and treatment medications, so Purdue could make money off the realities of dependence, addiction, and abuse—all of which McKinsey helped create. Following McKinsey's advice, Purdue's owner Dr. Richard Sackler received a patent for a drug to treat opioid addiction.

388. McKinsey also partnered with Purdue to test a program called FieldGuide, a proprietary software that McKinsey sought to license to other manufacturers. This software would enable other opioid manufacturers to target and aggressively pursue high-volume prescribers.

389. McKinsey continued to design and develop ways that Purdue could increase

sales of OxyContin well after the opioid epidemic peaked. As alluded to above, one proposal McKinsey recommended was for Purdue to pay "additional rebates on any new OxyContin related overdose or opioid use disorder diagnosis." McKinsey advised Purdue on its strategies to obtain and maintain broad formulary coverage for OxyContin with insurers and pharmacy benefit managers, even as payors began reducing coverage for OxyContin as the opioid crisis mounted.

390. Subsequently, in the wake of hundreds of thousands of opioid deaths and thousands of lawsuits, McKinsey proposed a plan for Purdue's exit from the opioid business whereby Purdue would continue selling opioids as a way to fund new Purdue ventures. According to McKinsey, this change was necessary because of the negative events that materially compromised the Purdue brand.

391. McKinsey's work for opioid manufacturers extended beyond Purdue. McKinsey collected millions of dollars designing and implementing marketing programs for the country's largest opioid manufacturers, including Johnson & Johnson and Endo, increasing the sale and use of opioids in Arizona and Bullhead City. McKinsey designed and implemented for other opioid manufacturers marketing plans similar to those it created for Purdue.

392. At the same time McKinsey was working for opioid companies, including the Manufacturer Defendants and the Distributor Defendants. McKinsey also consulted with governments and non-profits working to abate the raging opioid crisis—a crisis that McKinsey's own research showed was caused in large part by the massive spike in prescription opioids sales. Though McKinsey realized this increase was significantly attributable to the advice it was giving to the Defendants, McKinsey actively concealed its misconduct and even considered destroying documents relating to their consulting work for manufacturers, distributors and other businesses in the opioid industry.

393. In 2019, McKinsey announced that it no longer worked for Purdue or other opioid manufacturers. But the harm created by McKinsey's marketing plans for opioid manufacturers has not stopped.

394. Opioids have killed thousands in Bullhead City and across the State of Arizona, and continue to ravage the lives of many more. McKinsey, by devising the deceptive marketing strategies discussed above, both actively participated in creating one of the largest public health and safety crises in American history, and knowingly concealed material information that, had it been disclosed, could have prevented the opioid epidemic or reduced its severity.

395. Due to McKinsey's affirmative deception and fraudulent concealment, the opioid epidemic continues to rage in Bullhead City, and the ensuing opioid addiction and death has devastated, and continues to devastate, Plaintiff's communities. The economic toll on Bullhead City resulting from McKinsey's willful wrongdoing is equally grim. As detailed below, McKinsey misconduct has significantly increased the amount of money Bullhead City must spend to provide health care, child welfare and criminal justice services, along with many other programs that are necessary in order to abate the epidemic.

396. Months after McKinsey stopped its opioid work, Purdue filed for bankruptcy. More than a hundred thousand individuals filed claims for personal injuries. States and local governments filed claims for trillions of dollars incurred as a result of the opioid crisis. Another McKinsey client, opioid manufacturer Mallinckrodt plc, similarly filed for bankruptcy protection in October 2020.

397. In 2019, an Oklahoma state court found that McKinsey client Johnson & Johnson helped cause the opioid epidemic in Oklahoma, ordering it to pay $465 million to help abate the33. In 2020, Purdue pleaded guilty to three felonies as a result of conduct spanning a decade—from 2007 to 2017—during which Purdue worked side-by-side with McKinsey to design and implement marketing campaigns to increase dangerous opioid sales.

398. In 2020, Purdue and the members of the Sackler family who owned Purdue also settled civil claims by the Department of Justice for hundreds of millions of dollars. The materials filed in connection with that plea and settlement agreements contain a statement of facts regarding McKinsey's conduct and involvement in the conduct leading to the civil

claims against Purdue and the Sackler family.

399. Given McKinsey's role in designing, implementing, and aggressively furthering the common goal of the Opioid Marketing Enterprise, McKinsey is one of the most powerful—and dangerous—RICO Marketing Participants referenced in this complaint. Plaintiff respectfully requests the Court to treat McKinsey as such.

2. McKinsey Was An Architect of the Opioid Marketing Participants' Deceptive Marketing Campaign.

400. It is difficult to overstate the breadth of McKinsey's causal role in creating, worsening, and failing to mitigate the opioid epidemic that continues to decimate Bullhead City's communities. Indeed, McKinsey's misconduct is not limited to the Opioid Marketing Enterprise, but extends to Opioid Supply Chain Enterprise, as well. For this reason, McKinsey is considered a RICO Marketing Defendant and a RICO Supply Chain Defendant for purposes of this action.

401. Indeed, the structure and success of the RICO Supply Chain Participants' scheme—both of which are addressed below—are due in large part to the consulting services they received from McKinsey. On information and belief, McKinsey knowingly and intentionally sought to further the common goal of the Opioid Supply Chain in the following ways: (1) leveraging its previously existing relationship with top officials at the FDA, in order to convince the agency to dilute its "track and trace" system in 2017 and modify its rulemaking in a way that effectively allowed each RICO Supply Chain Defendant to misrepresent its compliance with anti-diversion laws and further the common goal of the Opioid Supply Chain Enterprise to illegally increase opioid sales—without triggering regulatory scrutiny; and (2) acting as a liaison between the RICO Supply Chain Participants and RICO Marketing Participants, developing deceptive strategies and encouraging the RICO Supply Chain Participants to implement them in order to maintain the illusion that RICO Supply Chain Participants were properly monitoring, reporting and stopping the shipment of suspicious opioid transactions.

402. In sum, McKinsey—in its capacity as a RICO Supply Chain Defendant—

conducted and/or participated in a systematically deceptive pattern and practice of racketeering activity, with the specific intent to unlawfully increase Defendants' opioid sales, including in Bullhead City. Because of the substantial investments McKinsey held in opioid addiction centers and overdose medications through its subsidiary, IMO Partners, McKinsey believed its financial interests were aligned with those of the other RICO Supply Chain Participants.

403. In sum, at all relevant times, McKinsey knew, and in fact intended, that Defendants' misconduct would lead to a surge of addiction and death. Rather than take action to prevent this tragedy, McKinsey actively facilitated the illegal goals of the Opioid Supply Chain Enterprise and worsened the opioid epidemic in Bullhead City, while also positioning itself to make substantial investment gains from the healthcare services that Bullhead City has to provide to treat opioid addiction in its communities and keep its citizens alive. McKinsey must be held accountable for its inexcusable misconduct, which—until recently—McKinsey successfully and intentionally concealed from Bullhead City and the general public.

L. RICO Supply Chain Participants Likewise Caused, Worsened, And Intentionally Failed to Stop the Opioid Epidemic in Bullhead City

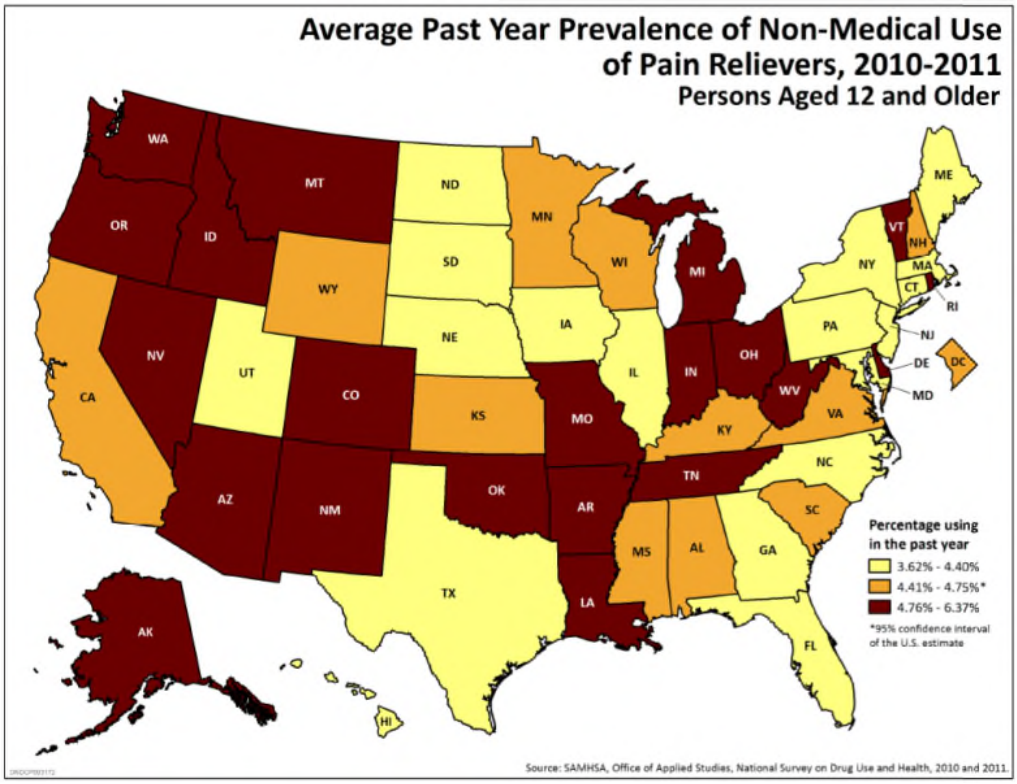
404. Under A.R.S. § 36-2523(A), all "[p]ersons registered to manufacture, distribute or dispense controlled substances"—*i.e.*, "Registrants"—are obligated to design and operate a system to disclose to the registrant suspicious orders of controlled substances, especially opioids. Each of the Distributor Defendants is a registrant for purposes of this section and, therefore, must satisfy certain reporting requirements of any and all "suspicious orders." Orders of controlled substances that are either unusual in size or frequency, or otherwise substantially deviate from a normal pattern, qualify as "suspicious orders."

405. As alleged below, it is clear that the RICO Marketing Participants, the Front Groups, and the KOLs were each willing participants in the Opioid Marketing Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose.

1. RICO Supply Chain Participants Facilitated Widespread Opioid Diversion

406. Opioid diversion in the supply chain has always been a widespread problem and has been highly publicized. Numerous publications, studies, federal agencies, Arizona agencies, and professional health organizations have highlighted the epidemic rate of opioid abuse and overdose rates in Bullhead City, as well as throughout the United States.

407. Prescription drug abuse is the fastest-growing drug problem in the United States, particularly in Arizona. In 2010-2011, 4/76%-6.37% of Arizonians engaged in non-medical use of pain relievers.



408. To combat the problem of opioid diversion, the DEA has provided guidance to distributors on the requirements of suspicious order reporting in numerous venues, publications, documents, and final agency actions.

409. Since 2006, the DEA has conducted one-on-one briefings with distributors regarding downstream customer sales, their due diligence responsibilities, and their legal and regulatory responsibilities (including the responsibility to know their customers and

report suspicious orders to the DEA). The DEA provided distributors with data on controlled substance distribution patterns and trends, including data on the volume of orders, frequency of orders, and percentage of controlled vs. non-controlled purchases. The distributors were also given case studies, legal findings against other registrants, and ARCOS profiles of their customers whose previous purchases may have reflected suspicious ordering patterns. The DEA pointed out "red flags" distributors should look for in order to identify potential diversion. This initiative was created to help distributors understand their duties with respect to diversion control.

410. Since 2007, the DEA has hosted at least five conferences to provide registrants with updated information about diversion trends and regulatory changes that affect the drug supply chain, the distributor initiative, and suspicious order reporting. All of the major distributors, including RICO Supply Chain Participants McKesson, AmerisourceBergen and Cardinal Health, attended at least one of these conferences. The conferences allowed the registrants to ask questions and raise concerns. These registrants could also request clarification on DEA policies and procedures.

411. Since 2008, the DEA has participated in numerous meetings and events with the legacy Healthcare Distribution Management Association ("HDMA"), now known as the Healthcare Distribution Alliance ("HDA"), an industry trade association for wholesalers and distributors. DEA representatives have provided guidance to the association concerning suspicious order monitoring, and the association has published guidance documents for its members on suspicious order monitoring, reporting requirements, and the diversion of controlled substances.[154]

412. On September 27, 2006 and again on December 27, 2007, the DEA Office of

[154] *See, e.g.*, HDA.org, Issues in Distribution, *Prescription Drug Abuse and Diversion* (2018) (describing various resources "address[ing] the industry's approach to countering diversion and ensuring the safe supply of medicines to licensed entities across the supply chain"), https://www.hda.org/issues/prescription-drug-abuse-and-diversion; *see also* HDMA, "Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances," (2008).

Diversion Control sent letters to all registered distributors providing guidance on suspicious order monitoring of controlled substances and the responsibilities and obligations of the registrant to conduct due diligence on controlled substance customers as part of a program to maintain effective controls against diversion. These letters reminded registrants that they were required by law to exercise due diligence to avoid filling orders that may be diverted into the illicit market. These letters explained that as part of the legal obligation to maintain effective controls against diversion, the distributor is required to exercise due care in confirming the legitimacy of all orders prior to filling.

413. On December 27, 2007, the Office of Diversion Control sent a follow-up letter to DEA registrants providing guidance and reinforcing the legal requirements outlined in the September 2006 correspondence. The December 2007 letter reminded registrants that suspicious orders must be reported when discovered and monthly transaction reports of excessive purchases did not meet the regulatory criteria for suspicious order reporting. The letter also advised registrants that they must perform an independent analysis of a suspicious order prior to the sale to determine if controlled substances would likely be diverted, and that filing a suspicious order and then completing the sale does not absolve the registrant from legal responsibility.

414. The RICO Supply Chain Participants were on notice that their own industry group, the Healthcare Distribution Management Association, published Industry Compliance Guidelines titled “Reporting Suspicious Orders and Preventing Diversion of Controlled Substances” that stressed the critical role of each member of the supply chain in distributing controlled substances.

415. Opioid distributors themselves recognized the magnitude of the problem and, at least rhetorically, their legal responsibilities to prevent diversion. They have made statements assuring the public they are supposedly undertaking a duty to curb the opioid epidemic.

416. For example, a Cardinal executive recently claimed that it uses “advanced analytics” to monitor its supply chain; Cardinal assured the public it was being “as effective

and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

417. McKesson has publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders" and claimed it is "deeply passionate about curbing the opioid epidemic in our country."

418. These assurances, in addition to obligations imposed by law, show that Distributor Defendants understand and have undertaken a duty to protect the public against diversion from their supply chains, and to curb the opioid epidemic.

419. However, despite these statements and duties, Distributor Defendants have knowingly or negligently allowed diversion. Their misconduct has resulted in numerous civil fines and other penalties recovered by state and federal agencies, including actions by the DEA.

420. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies. Again in 2012, AmerisourceBergen was implicated for failing to protect against the diversion of particular controlled substances into non-medically necessary channels. It has been reported that the U.S. Department of Justice has subpoenaed AmerisourceBergen for documents in connection with a grand jury proceeding seeking information on the company's "program for controlling and monitoring diversion of controlled substances into channels other than for legitimate medical, scientific and industrial purposes."

421. In 2008, Cardinal Health paid a $34 million penalty to settle allegations about opioid diversion taking place at seven warehouses around the United States. Again in 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states. Even very recently, in December 2016, a Department of Justice press release announced that, in connection with CSA violations, the United States reached a $34 million settlement for civil penalties under the CSA. During the investigation of Cardinal, the DEA discovered evidence that Cardinal's own investigator

warned Cardinal against selling opioids to a particular pharmacy in Florida that was suspected of opioid diversion. Cardinal took no action and failed to notify the DEA or cut off the supply of drugs to the pharmacy. Instead, Cardinal's opioid shipments to the pharmacy increased to almost 2 million doses of oxycodone in one year, while other comparable pharmacies were receiving approximately 69,000 doses/year.

422. In May 2008, McKesson entered into a settlement agreement with the DEA to settle claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the country, resulting in millions of doses of controlled substances being diverted. McKesson agreed to pay a $13.25 million civil fine. After 2008, McKesson still failed adhere to its duties and it was discovered that in Colorado, from 2008 to 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from only a single consumer. Early this year in 2017, it was reported that McKesson agreed to pay $150 million to the government to settle certain opioid diversion claims that it allowed drug diversion at 12 distribution centers in 11 states.

423. Although these RICO Supply Chain Participants have been penalized by law enforcement authorities, these penalties have not changed their conduct. They pay fines as a cost of doing business in an industry which generates billions of dollars in revenue.

424. The existence of these complicated regulatory schemes shows Defendants' intimate knowledge of the dangers of diversion of prescription opioids and the existence of a thriving illicit market for these drugs. Defendants breached their duties to Plaintiff despite this knowledge and longstanding regulatory guidance of how to deter and prevent diversion of prescription opioids.

425. The RICO Supply Chain Participants' individual and collective actions—which each RICO Supply Chain Defendant intentionally and specifically undertook to further their common goals in connection with the Opioid Supply Chain Enterprise—violated and continue to violate several Arizona anti-diversion statutes, including the

following:

- **A)** A.R.S. § 32-1983(B), stating that "[a] full service wholesale permittee may furnish prescription-only drugs to a pharmacy or medical practitioner. The full service wholesale permittee must first verify that person holds a valid license or permit."
- **B)** A.R.S. § 32-1983(C), mandating that,"[t]he full service wholesale permittee must deliver prescription-only drugs to an authorized person or agent of that premises if: (1) [t]he full service wholesale permittee properly establishes the person's identity and authority; and (2) [d]elivery to an authorized person or agent is used only to meet the immediate needs of a particular patient of the authorized person."
- **C)** A.R.S. § 32-1983(D), stating "[a] full service wholesale permittee may furnish prescription-only drugs to a pharmacy receiving area if a pharmacist or authorized receiving personnel sign, at the time of delivery, a receipt showing the type and quantity of the prescription-only drug received. Any discrepancy between receipt and the type and quantity of the prescription-only drug actually received must be reported to the full service wholesale permittee by the next business day after the delivery to the pharmacy receiving area."
- **D)** A.R.S. § 32-1983(E), mandating that "[a] full service wholesale permittee shall not accept payment for or allow the use of a person or entity's credit to establish an account for the purchase of prescription-only drugs from any other person other than the owner of record, the chief executive officer or the chief financial officer listed on the license or permit of a person or entity legally authorized to receive prescription-only drugs. Any account established for the purchase of prescription-only drugs must bear the name of the licensee or permittee."

426. In violating each and every one of these Arizona laws, the RICO Supply Chain

Participants have directly and proximately caused, continued and exacerbated a proliferation of dangerously addictive prescription opioids in Bullhead City. Distributor Defendants' misconduct has significantly and unreasonably interfered with the public health and safety in Bullhead City, by creating and continuing a public health and safety crisis, which has devastated Plaintiff's communities. As detailed below, the RICO Supply Chain Participants have also fostered a culture of opioid addiction and abuse in Bullhead City that manifests in many ways at Bullhead City's expense, including tax revenue expended incident to providing various public healthcare and criminal justice services that Bullhead City is required to provide to its citizens under Arizona law, as well as tax revenue forgone associated with opioid-related incapacitation (*e.g.*, specialty treatment, hospitalization, incarceration and death).

2. RICO Supply Chain Participants' Conduct and Role in Creating or Assisting in Creating the Opioid Epidemic Constitutes A "Pattern of Racketeering Activity," Which Is Not Excused by the Actions of Any Third Parties

427. Faced with the reality that they will now be held accountable for the consequences of the opioid epidemic they created, members of the industry resort to "a categorical denial of any criminal behavior or intent." The RICO Supply Chain Participants' actions went far beyond what could be considered ordinary business conduct. For more than a decade, the RICO Supply Chain Participants worked together in an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-competitive, with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding a market that the law intended to restrict.

428. Knowing that dangerous drugs have a limited place in our society, and that their dissemination and use must be vigilantly monitored and policed to prevent the harm that drug abuse and addiction causes to individuals, society and governments, the RICO Supply Chain Participants, driven by greed, willfully disregarded their duties as registrants under the CSA, and subverted the constraints of the CSA's closed system to conduct their

own enterprise for evil. Indeed, the RICO Supply Chain Participants, knowing that investigations into potential diversion would only lead to shrinking markets, elected to operate in a conspiracy of silence, in violation of both the CSA and RICO.

429. The RICO Supply Chain Participants' scheme required the participation of all. If even one member broke rank, its compliance activities would highlight deficiencies of the others, and the artificially high quotas they maintained through their scheme would crumble. But, if all the members of the enterprise conducted themselves in the same manner, it would be difficult for the DEA to go after any one of them. Accordingly, through the connections they made as a result of their participation in the "HAD," discussed above, the RICO Supply Chain Participants intentionally flouted the closed system designed to protect Bullhead City's citizens. While the RICO Supply Chain Participants' assured regulators and they were doing all they could to comply with anti-diversion laws, RICO Supply Chain Participants were secretly refusing to act and, through their lobbying efforts, collectively sought to undermine the impact of the CSA. Indeed, despite the issuance of these Industry Compliance Guidelines, the RICO Supply Chain Participants apparently all found the same profit-maximizing balance—intentionally remaining silent to ensure the largest possible financial return.

430. As described above, at all relevant times, the RICO Supply Chain Participants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by fraudulently increasing the quotas set by the DEA that would allow them to collectively benefit from a greater pool of prescription opioids to manufacture and distribute. In support of this common purpose and fraudulent scheme, the RICO Supply Chain Participants jointly agreed to disregard their statutory duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market so that those orders would not result in a decrease, or prevent an increase in, the necessary quotas.

431. For example, to further the common purpose of the Opioid Supply Chain Enterprise, RICO Marketing Participants intentionally and relentlessly disseminated the

following misrepresentations:

a. the quotas for prescription opioids should be increased;

b. they were complying with their obligations to maintain effective controls against diversion of their prescription opioids;

c. they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids;

d. they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids; and

e. they did not have the capability to identify suspicious orders of controlled substances.

432. When these misrepresentations were insufficient to achieve the goals of the Opioid Supply Chain Enterprise, the RICO Supply Chain Participants would resort to leveraging their political power and industry influence, both pressuring the DOJ and DEA to halt prosecutions of RICO Supply Chain Participants for failure to report suspicious orders of prescription opioids, as well as lobbying Congress to pass the "Ensuring Patient Access and Effective Drug Enforcement Act," which stripped the DEA of its ability to immediately suspend registrations pending investigation.

433. The CSA and the Code of Federal Regulations, require the RICO Supply Chain Participants to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders. The failure to make reports as required by the CSA and Code of Federal Regulations amounts to a criminal violation of the statute.

434. The RICO Supply Chain Participants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the DEA including the Marketing Participants' applications for production quotas. Specifically, the RICO Supply Chain Participants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market and

failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

435. The RICO Supply Chain Participants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

436. In devising and executing the illegal scheme, the RICO Supply Chain Participants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

437. For the purpose of executing the illegal scheme, the RICO Supply Chain Participants committed racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme. These racketeering acts, which included repeated acts of mail fraud and wire fraud, constituted a pattern of racketeering.

438. The RICO Supply Chain Participants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Marketing Participants, the Distributor Defendants, or third parties that were foreseeably caused to be sent as a result of the RICO Supply Chain Participants' illegal scheme, including but not limited to:

a. The prescription opioids themselves;

b. Documents and communications that supported and/or facilitated the RICO Supply Chain Participants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;

c. Documents and communications that facilitated the manufacture,

purchase and sale of prescription opioids;

d. RICO Supply Chain Participants' DEA registrations;

e. Documents and communications that supported and/or facilitated RICO Supply Chain Participants' DEA registrations;

f. RICO Supply Chain Participants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;

g. Documents and communications related to the RICO Supply Chain Participants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;

h. Documents intended to facilitate the manufacture and distribution of the RICO Supply Chain Participants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;

i. Documents for processing and receiving payment for prescription opioids;

j. Payments from the Distributors to the Marketing Participants;

k. Rebates and chargebacks from the Marketing Participants to the Distributors Defendants; l. Payments to the RICO Supply Chain Participants' lobbyists through the PCF;

m. Payments to the RICO Supply Chain Participants' trade organizations, like the HDA, for memberships and/or sponsorships;

n. Deposits of proceeds from the RICO Supply Chain Participants' manufacture and distribution of prescription opioids; and

o. Other documents and things, including electronic communications.

439. The RICO Supply Chain Participants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by

mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce.

440. Each of the RICO Supply Chain Participants identified, shipped, paid for and received payment for the Manufacturer Defendants prescription opioids, throughout the United States.

441. Further, the RICO Supply Chain Participants used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities, namely by misrepresenting their compliance with Federal and state laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

442. The RICO Supply Chain Participants also utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

443. At the same time, the RICO Supply Chain Participants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and their compliance with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

444. The RICO Supply Chain Participants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail with each other and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

445. The mail and wire transmissions described herein were made in furtherance of the RICO Supply Chain Participants' scheme and common course of conduct to deceive regulators, the public and the Plaintiff that these Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The RICO Supply Chain Participants' scheme and

common course of conduct was to increase or maintain high production quotas for their prescription opioids from which they could profit.

446. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden by Defendants and cannot be alleged without access to Defendants' books and records. However, Plaintiff has described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

447. The RICO Supply Chain Participants did not undertake the practices described herein in isolation, but as part of a common scheme. Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with these Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the RICO Supply Chain Participants.

448. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

449. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiff's business and property, while simultaneously generating billions in revenue for themselves and the other members of the Opioid Supply Chain Enterprise.

M. Each of the Defendant's Misconduct Has Injured and Continues to Injure Bullhead City and Its Citizens

450. In addition to the significant social costs associated with illicit drug use, Defendants' predatory and willful misrepresentations in manufacturing, marketing and/or distributing opioids have imposed enormous tax-based economic damages on Bullhead City,

including tax revenue expended incident to providing various public services that Bullhead City is required to provide to its citizens under Arizona law, including healthcare- and crime-related costs. These revenues would not have been expended but for the opioid crisis that Defendants willfully and foreseeably caused in Arizona generally and Bullhead City specifically.

451. As Defendants' opioids continue to wreak havoc on Bullhead City's community and incapacitate and/or kill Bullhead City's citizens, Bullhead City has also been deprived of the benefits these citizens would have conferred to the community but for Defendants' wrongful conduct. Bullhead City has lost both the productivity of Bullhead City's citizens who have been hospitalized, incarcerated, killed, or otherwise incapacitated by Defendants' dangerous products, including the property and/or sales taxes these citizens would have paid had Defendants' simply told the truth about the risks and benefits of opioids.

1. Tax Revenue Expended—Healthcare-Related Costs

452. Drugs kill more Arizonans each year than motor vehicle accidents.[155] According to the CDC, the number of drug-related deaths in Arizona is among the highest in the nation and continues to increase each year. Even within Arizona, the risk of drug-related death is particularly high in Mohave County, which the Office of National Drug Control Policy ("ONDCP") considers a High Intensity Drug Tracking Area ("HIDTA").[156]

453. While Defendants reaped billions of dollars in profits from their deceptive conduct, Bullhead City suffered—and continues to suffer—irreparable damage in the form of increased healthcare-related costs, which Arizona law requires that Bullhead City pay to protect the health and safety of its citizenry. Bullhead City would not have incurred these costs had Defendants not concealed the true dangers (and misrepresented the true benefits)

[155] Executive Office of the President of the United States, *Arizona Drug Control Update - 2010*, p. 1 (2010), https://obamawhitehouse.archives.gov/sites/default/files/docs/state_profile-arizona.pdf.

[156] Exec. Office of the Pres. of the U.S., *Arizona Drug Control Update – 2010*, p. 7 (2010), https://obamawhitehouse.archives.gov/sites/default/files/docs/state_profile-arizona.pdf.

of the relevant opioids.

454. Specifically, each of the Defendants has directly and proximately caused Plaintiff to divert precious tax dollars and local resources to address its citizens' ever-increasing need for (a) specialty services—*e.g.*, detoxification, residential, inpatient and outpatient methadone programs; (b) hospital and emergency medical services; and (c) foster care services.

(a) Emergency Medical Treatment—Opioid-Related Emergencies

455. The number of opioid-related encounters in Arizona hospitals increased from 20,365 in 2009 to 51,473 in 2016—an increase of roughly 153%.[157] Opioids have a significant impact upon Arizona's medical care system due to the volume of encounters involving opioids, and the costs of these encounters. While the full economic burden of opioids upon the healthcare system is difficult to precisely calculate, a reasonable measure may be derived using hospital reported charges adjusted using national cost to charges ratios provided by the Department of Health and Human Services. Using this approach, the cost of all 'opioid-related' encounters in Arizona from 2009-2015 increased by 125% and—in 2016—equaled $341,457.011.[158] The average cost per opioid-related unique encounter is $8,241.[159]

456. On information and belief, the incidence of opioid-related hospitalizations in Bullhead City — which can be tracked by various medical billing and documentation codes, such as the Healthcare Common Procedure Coding System ("HCPCS") and the American Medical Association's Current Procedural Terminology (CPT), including National Drug

---

[157] Arizona Department of Health Services, *2016 Arizona Opioid Report*, p. 5-6 (2016), https://www.azdhs.gov/documents/audiences/clinicians/clinical-guidelines-recommendations/prescribing-guidelines/arizona-opioid-report.pdf

[158] Arizona Department of Health Services, *2016 Arizona Opioid Report*, p. 5 (2016), https://www.azdhs.gov/documents/audiences/clinicians/clinical-guidelines-recommendations/prescribing-guidelines/arizona-opioid-report.pdf

[159] *Id.*, *supra*, n. 216 at p. 6.

Codes ("NDCs") and International Classification of Diseases ("ICD") codes—similarly increased during the relevant period. As the number of opioid-related hospital encounters in Arizona has ballooned, the costs of treatment and supplies have also increased by at least 125%.[160] The number of emergency 911 calls in Bullhead City also increased from 64,865 in 2014 to 67,919 calls in 2016.[161]

(b) Foster Care Placement and Other Family Services

457. Defendants' actions that fueled the opioid crisis have also devastated many American families, and the child welfare system has felt the effects. Between 2010 and 2012, after more than a decade of sustained declines in the national foster care caseload, the number of children entering foster care started to rise—just as opioid deaths began to spike.[162] Today, more than 258,000 children are in the foster care system nationwide, nearly 18,000 of which are right here in Arizona.[163]

458. Arizona's foster-care system is designed to protect children from abuse and neglect, removing children from their homes if they face an "unreasonable risk of harm."[164]

---

[160] Arizona Department of Health Services, *2016 Arizona Opioid Report*, p. 5-6 (2016), https://www.azdhs.gov/documents/audiences/clinicians/clinical-guidelines-recommendations/prescribing-guidelines/arizona-opioid-report.pdf

[161] Bullhead City, *Adopted Budget Fiscal Year 2015-16*, p. 51, https://www.bullheadcity.com/home/showdocument?id=4253; Bullhead City, *Adopted Budget Fiscal Year 2018-19*, p. 58, https://www.bullheadcity.com/home/showdocument?id=12793.)

[162] Laura Radel, *Substance Use, the Opioid Epidemic, and the Child Welfare System: Key Findings from a Mixed Methods Study*, U.S. Dept. of Health and Human Services, p. 2 (Mar. 7, 2018), https://aspe.hhs.gov/system/files/pdf/258836/SubstanceUseChildWelfareOverview.pdf

[163] Mary Jo Pitzl, '*Biggest challenge, biggest opportunity*': DCS aims to keep more kids at home, THE ARIZONA REPUBLIC (Feb. 4, 2018), https://www.azcentral.com/story/news/local/arizona-investigations/2018/02/04/child-welfare-agency-policy-aims-clearly-define-when-safe-leave-kids-home/881208001/

[164] Bob Ortega, *A Horrifying Journey through Arizona foster care, and why we don't know how many more children may be abused*, THE ARIZONA REPUBLIC (June 4, 2017), https://www.azcentral.com/story/news/local/arizona-investigations/2017/06/04/arizona-foster-care-child-abuse/362836001/

The Arizona Department of Child Safety ("ADCS") defines "unreasonable risk of harm" to mean that "the totality of the circumstances specific to the incident, the behavior and/or action or inaction of the parent, guardian or custodian placed the child at a level of risk of harm to which a reasonable (ordinarily cautious) parent, guardian or custodian would not have subjected the child."[165] ADCS has characterized the increase in opioid-related cases in emergency departments as "alarming," and the Arizona Substance Abuse Partnership ("ASAP") has likewise recognized the importance of removing a child living in home in which opioid abuse is occurring.

459. The number of Arizona children that are removed from their homes by the state foster care system—*i.e.*, the "Removal Rate"—is about three-times higher than the national average.[166] Moreover, from 2013 to 2016, the Removal Rate increased by roughly 30 percent[167]—well outside the normal range, even for states hit hardest by the opioid epidemic,[168] and after factoring in Arizona's high childhood poverty rate.[169] As a result, Arizona child welfare agencies and their community partners are struggling to meet families'

---

[165] Department of Economic Security—Division of Children Youth and Families, *Child and Family Services: Annual Progress Report 2012, State of Arizona*, p. 225 (June, 2012), https://dcs.az.gov/file/5405/download?token= 1ZRcWAmV

[166] B. Ortega, *Arizona's DCS: Why are kids taken away? Too often the answer is unknown*, THE ARIZONA REPUBLIC (Mar. 14, 2017), https://www.azcentral.com/story/news/local/arizona-investigations/2017/01/22/arizona-department-child-safety-why-kids-taken-away-too-often-answer-unknown/96539080/; *see also* L. Radel, *supra*, Note 176 at p. 8 ("Child welfare caseloads nationally increased by 10 percent between fiscal years 2012 and 2016.")

[167] Nicole Carrol, *Arizona child welfare: There are some issues we just won't let go*, THE ARIZONA REPUBLIC (Aug. 28, 2016), https://www.azcentral.com/story/news/local/arizona-investigations/2016/08/28/arizona-child-welfare-there-some-issues-we-just-wont-let-go/89313770/.

[168] E. Birnbaum, *Opioid crisis sending thousands of children into foster care*, THE HILL (June 20, 2018), https://thehill.com/policy/healthcare/393129-opioid-crisis-sending-thousands-of-children-into-foster-care

[169] Emily Bregel, *Despite state progress in Arizona, 'a lot of desperation, isolation'*, ARIZONA DAILY STAR (Mar. 9, 2018), https://tucson.com/news/local/despite-state-progress-in-arizona-a-lot-of-desperation-isolation/article_fb7af064-224b-11e8-a96b-fbbdaba17d9c.html

needs, including in Bullhead City, with many counties experiencing at least a 50% increase in their respective caseloads and local agencies reporting family members across multiple generations are more frequently becoming addicted to, or dying from, opioids.[170]

460. Consistent with the above, in March of 2018 the U.S. Department of Health and Human Services ("DHHS") confirmed that "the high levels of opioid sales and drug overdose deaths spreading across the nation in recent years raise the concern that additional counties may experience increased child welfare caseloads in the coming years."[171] DHHS reported that, while drug-related hospitalization rates vary widely between substances such as opioids, stimulants and hallucinogens, the opposite is true with respect to foster care, such that "a 10 percent increase in hospitalizations due to any of these substance types corresponded with approximately a 2 percent increase in foster care entry rates."[172]

461. To address the demand for foster care services in Bullhead City resulting from the opioid epidemic, Plaintiff funds—*inter alia*—the Bullhead City Police Crime Victim Services Unit ("CVSU"), which provides a variety of services to crime victims, including minors who are victims of neglect and abuse.[173]

2. Tax Revenue Expended—Crime-Related Costs

462. In addition to imposing on Plaintiff significantly higher healthcare-related costs, Defendants' scheme has spread thin Plaintiff's resources by causing a sharp uptick in criminal justice costs, including those associated with opioid-related arrests, investigations and other local police programs. The funds necessary to maintain the day-to-day operating expenses and equipment for these programs come from Plaintiff's general revenues, including Plaintiff's revenues from Plaintiff's privilege (sales) taxes and property taxes.[174]

---

[170] *See* L. Radel, *supra*, Note 176 at p. 4.

[171] *See* L. Radel, *supra*, Note 176 at p. 8-9.

[172] *See* L. Radel, *supra*, Note 176 at p. 4-5.

[173] https://www.bullheadcity.com/departments/city-prosecutor-s-office/crime-victim-services

[174] Bullhead City, *Comprehensive Annual Financial Report 2018-19*, https://www.bullheadcity.com/departments/finance/financial-reports/budget-reports

463. Because Plaintiff finances the operation of the Bullhead City Police Department through the city's General Fund, the increased burden on the Bullhead City Police Department resulting from Defendants' misconduct has likewise damaged Plaintiff. Moreover, Plaintiff's police expenditures for 2019 are budgeted to exceed those in 2017 by almost $2 million.[175]

(a) Arrests and Investigations to Protect Public Health and Safety

464. The effects of Defendants' deceptive marketing and distribution scheme has further impacted Plaintiff by creating various public nuisances—including public health and safety hazards—which Plaintiff is obligated to abate. Plaintiff has dedicated substantial tax dollars to maintain the public safety of places, such as city parks, schools and public lands, where patients-turned-addicts attempt to congregate. Plaintiff has also dedicated significant funds to enable the Bullhead City Police Department to mitigate the increase in drug and property crimes committed by opioid addicts who are both actively looking to feed their addictions, as well as suffering from serious medical conditions associated with the spread opioid abuse, such as Hepatitis B and C, HIV, sexually transmitted diseases and methicillin-resistant staphylococcus aureus ("MRSA"), among other conditions..

465. For example, Plaintiff finances the general operations of the Bullhead City Police Department. These operations include opioid overdose cases that require the dedicated time of several police officers to conduct investigations, make arrests, execute search warrants, facilitate bookings, write reports, impound evidence, provide scene security and follow up, among other things. The public nuisance that the Defendants created has burdened and continues to burden the Bullhead City Police Department's operations to protect the health and safety of Plaintiff's residents from the ongoing opioid epidemic.

466. In abating the opioid epidemic to protect the health and safety of citizens of Bullhead City, Plaintiff has suffered pecuniary damages, proximately caused by each

[175] *Id.*, at p. 17; Bullhead City, *Comprehensive Annual Financial Report 2016-17,* https://www.bullheadcity.com/departments/finance/financial-reports/budget-reports

Defendants' misrepresentations and omissions of material fact.

(b) Community Services—Crime Victim Services Unit

467. Plaintiff also dedicates significant portions of its general revenues to enable the Bullhead City Police Department to protect the health and safety of its citizens, including through the CVSU. The CVSU can provide services to victims of crime inclusive of intimate partner and domestic violence, sexual assault and child abuse.

468. In addition, Plaintiff's advocates work with victims of crime helping connect them with community resources for shelter, food, clothing, etc., assisting in navigating the criminal justice system, and ensuring their rights as a victim are being honored. These advocates can act as a liaison between the victim and various agencies involved, not only keeping the victim informed, but giving them a voice.

469. As the utilization of the CVSU by Bullhead City's citizens has increased over the years of the opioid crisis, so too have Plaintiff's allocations to maintain these important public programs and maintain the health and safety of Plaintiff's citizens.

3. Tax Revenue Forgone

470. Tax revenue forgone is a consequence of incapacitation. The principal events associated with incapacitation include specialty treatment, hospitalization, incarceration and death. As a result of such incapacitation, the citizens of Bullhead City who became addicted to Defendants' opioids are unable to work or contribute to Bullhead City's financial health through sales, property and other taxes.

471. Indeed, the amount of revenue that Bullhead City has received from the Urban Revenue Sharing Program ("URSP") went down every year from 2008-2011, decreasing from a high of over $5.7 million in 2008 to roughly $3.34 million in 2011[176]. Today, the amount of revenue Bullhead City expects to receive from the URSP remains significantly less than what the City received in 2008.[177]

---

[176] Bullhead City, *Adopted Budget Fiscal Year 2018-19*, p. 43, https://www.bullheadcity.com/home/showdocument?id=12793.

[177] *Id.*

472. As set forth below, Defendants' willful, dishonest scheme made it much more difficult—and significantly more expensive—for Plaintiff to ameliorate its tax-related damages associated with the incapacitation of both its citizens and others who either died in Bullhead City, or were incapacitated in Bullhead City due to specialty treatment and/or hospital services.

(a) Hospitalization

473. Patients who are hospitalized in connection with opioid-related emergencies are likewise unable to contribute to Bullhead City's financial health with their labor or through the payment of taxes. Indeed, in 2018 the Arizona Department of Public Health reported that 97% of patients suffering from an opioid-related emergency survived the immediate pre-hospital event.[178] Moreover, according to a 2018 report published by DHHS, opioid-related hospital stays were consistently longer than those attributable to both hallucinogens and stimulants, including cocaine and methamphetamine.[179] Longer hospital stays are usually more expensive and lead to larger losses of productivity for the hospitalized patient.

474. Even if patients survive the immediate pre-hospital event and are successfully stabilized at, and discharged from, the treating hospital, these patients are frequently referred to specialty treatment facilities in Bullhead City and continue to be incapacitated by their addictions.

(b) Death

475. According to government estimates, some 50,000 Americans died from an opioid overdose in 2016—*i.e.*, 137 people per day, and roughly one person every 12 minutes.[180] The emotional devastation caused by Defendants' despicable actions is impossible to quantify; however, as described above, the purely economic consequences of the opioid

---

[178] *Id.*

[179] *See* L. Radel, *supra*, Note 176 at p. 4.

[180] Money.com, *Here's What I Would Cost to Fix the Opioid Crisis, According to 5 Experts* (Nov. 27, 2017), http://money.com/money/5032445/cost-fix-opioid-crisis/.

epidemic can and have been successfully tracked in terms of lives, lost productivity, healthcare, criminal justice and other costs. Accordingly, in 2017 President Donald Trump's Council of Economic Advisers estimated that the economic consequences to the nation of the opioid drug epidemic cost the United States $504 billion in 2015 alone, prompting the President to declare the opioid crisis a nationwide public health emergency.

476. Plaintiff has been hit even harder by the opioid crisis. In the past decade, 5,932 Arizonans died from opioid-induced causes, including many residents of Bullhead City who would not have died but for the Defendants' misconduct as described in this Complaint.

477. Finally, the opioid crisis has been particularly devastating to Bullhead City's ability to generate tax revenue. From 2006 to 2016, more opioid-related deaths occurred in Arizona for people in their economic primes—*i.e.*, ages 45-54—than for any other age group.[181] Plaintiff has suffered—and continues to suffer—from this deleterious trend, as the number of overdose deaths in Bullhead City continues to increase as a direct and proximate result of the Defendants' misdeeds.

V. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Violation of RICO, 18 U.S.C. § 1961 *et seq.*—"Opioid Marketing Enterprise"

(Against Manufacturer Defendants ("RICO Marketing Participants[182]"))

478. Plaintiff repeats, re-alleges, and incorporates by reference each and every allegation set forth above as if fully set forth herein.

479. The RICO Marketing Participants—through the use of "Front Groups" that appeared to be independent of the RICO Marketing Participants; through the dissemination of publications that supported the RICO Marketing Participants' scheme; through continuing medical education ("CME") programs controlled and/or funded by the RICO Marketing

[181] Arizona Department of Health Services, *2016 Arizona Opioid Report*, p. 2 (2016), https://www.azdhs.gov/documents/audiences/clinicians/clinical-guidelines-recommendations/prescribing-guidelines/arizona-opioid-report.pdf ("By age, opioid death rates rise beginning in the late teens until they peak at age 45-54.").

[182] Excluding McKinsey for the time being.

Participants; by the hiring and deployment of so-called "key opinion leaders," ("KOLs") who were paid by the RICO Marketing Participants to promote their message; and through the "detailing" activities of the RICO Marketing Participants' sales forces—conducted an association-in-fact enterprise, and/or participated in the conduct of an enterprise through a pattern of illegal activities (the predicate racketeering acts of mail and wire fraud) to carry-out the common purpose of the Opioid Marketing Enterprise, *i.e.*, to unlawfully increase profits and revenues from the continued prescription and use of opioids for chronic pain. Through the racketeering activities of the Opioid Marketing Enterprise sought to further the common purpose of the enterprise through a fraudulent scheme to change prescriber habits and public perception about the safety and efficacy of opioid use by convincing them that each of the nine false propositions alleged earlier were true. In so doing, each of the RICO Marketing Participants knowingly conducted and participated in the conduct of the Opioid Marketing Activities by engaging in mail and wire fraud in violation of 18 U.S.C. §§ 1962(c) and (d).

480. The Opioid Marketing Enterprise alleged above, is an association-in-fact enterprise that consists of the RICO Marketing Participants; the Front Groups (APF, AAPM, APS, FSMB, USPF, and AGS); and the KOLs (Dr. Portenoy, Dr. Webster, Dr. Fine, and Dr. Fishman).

481. Each of the RICO Marketing Participants and the other members of the Opioid Marketing Enterprise conducted and participated in the conduct of the Opioid Marketing Enterprise by playing a distinct role in furthering the enterprise's common purpose of increasing profits and sales through the knowing and intentional dissemination of false and misleading information about the safety and efficacy of long-term opioid use, and the risks and symptoms of addiction, in order increase the market for prescription opioids by changing prescriber habits and public perceptions and increase the market for opioids.

482. Specifically, the RICO Marketing Participants each worked together to coordinate the enterprise's goals and conceal their role, and the enterprise's existence, from the public by, among other things, (i) funding, editing and distributing publications that

supported and advanced their false messages; (ii) funding KOLs to further promote their false messages; (iii) funding, editing and distributing CME programs to advance their false messages; and (iv) tasking their own employees to direct deceptive marketing materials and pitches directly at physicians and, in particular, at physicians lacking the expertise of pain care specialists (*i.e.*, "detailing").

483. Each of the Front Groups helped disguise the role of RICO Marketing Participants by purporting to be unbiased, independent patient-advocacy and professional organizations in order to disseminate patient education materials, a body of biased and unsupported scientific "literature," and "treatment guidelines" that promoted the RICO Marketing Participants false messages.

484. Each of the KOLs were physicians chosen and paid by each of the RICO Marketing Participants to influence their peers' medical practice by promoting the Marketing Defendant's false message through, among other things, writing favorable journal articles and delivering supportive CMEs as if they were independent medical professionals, thereby further obscuring the RICO Marketing Participants' role in the enterprise and the enterprise's existence.

485. Further, each of the RICO Marketing Participants, KOLs and Front Groups that made-up the Opioid Marketing Enterprise had systematic links to and personal relationships with each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. The systematic links and personal relationships that were formed and developed allowed members of the Opioid Marketing Enterprise the opportunity to form the common purpose and agree to conduct and participate in the conduct of the Opioid Marketing Enterprise. Specifically each of the RICO Marketing Participants coordinated their efforts through the same KOLs and Front Groups, based on their agreement and understanding that the Front Groups and KOLs were industry friendly and would work together with the RICO Marketing Participants to advance the common purpose of the Opioid Marketing Enterprise; each of the individuals and entities who formed the Opioid Marketing Enterprise acted to enable the

common purpose and fraudulent scheme of the Opioid Marketing Enterprise.

486. At all relevant times, the Opioid Marketing Enterprise: (a) had an existence separate and distinct from each RICO Marketing Defendant and its members; (b) was separate and distinct from the pattern of racketeering in which the RICO Marketing Participants engaged; (c) was an ongoing and continuing organization consisting of individuals, persons, and legal entities, including each of the RICO Marketing Participants; (d) was characterized by interpersonal relationships between and among each member of the Opioid Marketing Enterprise, including between the RICO Marketing Participants and each of the Front Groups and KOLs; (e) had sufficient longevity for the enterprise to pursue its purpose and functioned as a continuing unit.

487. The persons and entities engaged in the Opioid Marketing Enterprise are systematically linked through contractual relationships, financial ties, personal relationships, and continuing coordination of activities, as spearheaded by the RICO Marketing Participants.

488. The RICO Marketing Participants conducted and participated in the conduct of the Opioid Marketing Enterprise through a pattern of racketeering activity that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud), to increase profits and revenue by changing prescriber habits and public perceptions in order to increase the prescription and use of prescription opioids, and expand the market for opioids.

489. The RICO Marketing Participants each committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Marketing Participants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Marketing Participants' regular use of the facilities, services, distribution channels, and employees of the Opioid Marketing

Enterprise, the U.S. Mail and interstate wire facilities. The RICO Marketing Participants participated in the scheme to defraud by using mail, telephones and the Internet to transmit mailings and wires in interstate or foreign commerce.

490. The RICO Marketing Participants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a. Mail Fraud: The RICO Marketing Participants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

b. Wire Fraud: The RICO Marketing Participants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

491. Indeed, as alleged herein, the RICO Marketing Participants used the mail and wires to send or receive thousands of communications, publications, representations, statements, electronic transmissions and payments to carry-out the Opioid Marketing Enterprise's fraudulent scheme.

492. Because the RICO Marketing Participants disguised their participation in the enterprise, and worked to keep even the enterprise's existence secret so as to give the false appearance that their false messages reflected the views of independent third parties, many of the precise dates of the Opioid Marketing Enterprise's uses of the U.S. Mail and interstate wire facilities (and corresponding predicate acts of mail and wire fraud) have been hidden

and cannot be alleged without access to the books and records maintained by the RICO Marketing Participants, Front Groups, and KOLs. Indeed, an essential part of the successful operation of the Opioid Marketing Enterprise alleged herein depended upon secrecy. However, Plaintiff has described the occasions on which the RICO Marketing Participants, Front Groups, and KOLs disseminated misrepresentations and false statements to Montana consumers, prescribers, regulators and Plaintiff, and how those acts were in furtherance of the scheme.

493. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Bullhead City consumers, prescribers, regulators and Plaintiff. The RICO Marketing Participants, Front Groups and KOLs calculated and intentionally crafted the scheme and common purpose of the Opioid Marketing Enterprise to ensure their own profits remained high. In designing and implementing the scheme, the RICO Marketing Participants understood and intended that those in the distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and scientific evidence regarding the RICO Marketing Participants' products.

494. The RICO Marketing Participants' pattern of racketeering activity alleged herein and the Opioid Marketing Enterprise are separate and distinct from each other. Likewise, the RICO Marketing Participants are distinct from the Opioid Marketing Enterprise.

495. The pattern of racketeering activity alleged herein is continuing as of the date of this complaint, and, upon information and belief, will continue into the future unless enjoined by this Court.

496. The racketeering activities conducted by the RICO Marketing Participants, Front Groups and KOLs amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive Montana consumers, prescribers, regulators and the Plaintiff. Each separate use of the U.S. Mail and/or interstate wire facilities employed by

Defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Montana consumers, prescribers, regulators and the Plaintiff. The RICO Marketing Participants have engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the Opioid Marketing Enterprise.

497. Each of the RICO Marketing Participants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

498. As described herein, the RICO Marketing Participants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant money and revenue from the marketing and sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

499. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

500. The RICO Marketing Participants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property. The RICO Marketing Participants' pattern of racketeering activity logically, substantially and foreseeably caused an opioid epidemic. Plaintiff's injuries, as described below, were not unexpected, unforeseen or independent. Rather, as Plaintiff alleges, the RICO Marketing Participants knew that the opioids were unsuited to treatment of chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse. Nevertheless, the RICO Marketing Participants engaged in a scheme of deception that utilized the mail and wires in order to carry-out the Opioid Marketing Enterprises' fraudulent scheme, thereby increasing sales of

their opioid products.

501. It was foreseeable and expected that the RICO Marketing Participants creating and then participating in the Opioid Marketing Enterprise through a pattern of racketeering activities to carry-out their fraudulent scheme would lead to a nationwide opioid epidemic, including increased opioid addiction and overdose.

502. Specifically, the RICO Marketing Participants' creation of, and then participation in, the Opioid Marketing Enterprise through a pattern of racketeering activities to carry-out their fraudulent scheme has injured Plaintiff in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic. Plaintiff's injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include:

a. Losses caused by the decrease in funding available for Plaintiff's public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;

b. Costs for providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;

c. Costs of training emergency and/or first responders in the proper treatment of drug overdoses;

d. Costs associated with providing police officers, firefighters, and emergency and/or first responders with naloxone – an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

e. Costs associated with emergency responses by police officers, firefighters, and emergency and/or first responders to opioid overdoses;

f. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;

g. Costs for providing treatment of infants born with opioid-related medical

conditions, or born addicted to opioids due to drug use by mother during pregnancy;

h. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population;

i. Costs associated with increased burden on Plaintiff's judicial system, including increased security, increased staff, and the increased cost of adjudicating criminal matters due to the increase in crime directly resulting from opioid addiction;

j. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation;

k. Loss of tax revenue due to the decreased efficiency and size of the working population in Plaintiff's Community;

l. Loss of productivity and economic opportunity;

m. Costs associated with extensive clean-up of public parks, spaces, and facilities of needles and other debris and detritus of opioid addiction;

n. Losses caused by diminished property values in neighborhoods where the opioid epidemic has taken root; and

o. Losses caused by diminished property values in the form of decreased business investment and tax revenue.

503. Plaintiff's injuries were directly and thus proximately caused by these Defendants' racketeering activities because they were the logical, substantial and foreseeable cause of Plaintiff's injuries. But for the opioid-addiction epidemic the RICO Marketing Participants created through their Opioid Marketing Enterprise, Plaintiff would not have lost money or property.

504. Plaintiff is the most directly harmed entity and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

505. Plaintiff seeks all legal and equitable relief as allowed by law, including, inter alia, actual damages; treble damages; equitable and/or injunctive relief in the form of court-supervised corrective communication, actions and programs; forfeiture as deemed proper by the Court; attorney's fees; all costs and expenses of suit; and pre- and post-judgment interest, including, *inter alia*:

a. Actual damages and treble damages, including pre-suit and post-judgment interest;

b. An order enjoining any further violations of RICO;

c. An order enjoining any further violations of any statutes alleged to have been violated in this Complaint;

d. An order enjoining the commission of any tortious conduct, as alleged in this Complaint;

e. An order enjoining any future marketing or misrepresentations regarding the health benefits or risks of prescription opioids use, except as specifically approved by the FDA;

f. An order enjoining any future marketing of opioids through non-branded marketing including through the Front Groups, KOLs, websites, or in any other manner alleged in this Complaint that deviates from the manner or method in which such marketing has been approved by the FDA;

g. An order enjoining any future marketing to vulnerable populations, including but not limited to, persons over the age of fifty-five, anyone under the age of twenty-one, and veterans;

h. An order compelling the Defendants to make corrective advertising statements that shall be made in the form, manner and duration as determined by the Court, but not less than print advertisements in national and regional newspapers and medical journals, televised broadcast on major television

networks, and displayed on their websites, concerning: (1) the risk of addiction among patients taking opioids for pain; (2) the ability to manage the risk of addiction; (3) pseudoaddiction is really addiction, not a sign of undertreated addiction; (4) withdrawal from opioids is not easily managed; (5) increasing opioid dosing presents significant risks, including addiction and overdose; (6) long-term use of opioids has no demonstrated improvement of unction; (8) use of time-released opioids does not prevent addiction; (9) abuse-deterrent formulations do not prevent opioid abuse; and (10) that manufacturers and distributors have duties under the CSA to monitor, identify, investigate, report and halt suspicious orders and diversion but failed to do so;

i. An order enjoining any future lobbying or legislative efforts regarding the manufacturer, marketing, distribution, diversion, prescription, or use of opioids;

j. An order requiring all Defendants to publicly disclose all documents, communications, records, data, information, research or studies concerning the health risks or benefits of opioid use;

k. An order prohibiting all Defendants from entering into any new payment or sponsorship agreement with, or related to, any: Front Group, trade association, doctor, speaker, CME, or any other person, entity, or association, regarding the manufacturer, marketing, distribution, diversion, prescription, or use of opioids;

l. An order establishing a National Foundation for education, research, publication, scholarship, and dissemination of information regarding the health risks of opioid use and abuse to be financed by the Defendants in an amount to be determined by the Court;

m. An order enjoining any diversion of opioids or any failure to monitor, identify, investigate, report and halt suspicious orders or diversion of opioids;

n. An order requiring all Defendants to publicly disclose all documents,

communications, records, information, or data, regarding any prescriber, facility, pharmacy, clinic, hospital, manufacturer, distributor, person, entity or association regarding suspicious orders for or the diversion of opioids;

o. An order divesting each Defendant of any interest in, and the proceeds of any interest in, the Marketing and Supply Chain Enterprises, including any interest in property associated with the Marketing and Supply Chain Enterprises;

p. Dissolution and/or reorganization of any trade industry organization, Front Group, or any other entity or association associated with the Marketing and Supply Chain Enterprises identified in this Complaint, as the Court sees fit;

q. Dissolution and/or reorganization of any Defendant named in this Complaint as the Court sees fit;

r. Suspension and/or revocation of the license, registration, permit, or prior approval granted to any Defendant, entity, association or enterprise named in the Complaint regarding the manufacture or distribution of opioids;

s. Forfeiture as deemed appropriate by the Court; and t. Attorney's fees and all costs and expenses of suit.

SECOND CLAIM FOR RELIEF

Violation of RICO, 18 U.S.C. § 1961 et seq. – Opioid Supply Chain Enterprise (Against Manufacturer Defendants; Distributor Defendants(the "RICO Supply Chain Participants[183]"))

506. Plaintiff repeats, re-alleges, and incorporates by reference each and every allegation set forth above as if fully set forth herein. 857. At all relevant times, the RICO Supply Chain Participants were and are "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

507. The RICO Supply Chain Participants together formed an association-in-fact

[183] Excluding McKinsey for the time being.

enterprise, the Opioid Supply Chain Enterprise, for the purpose of increasing the quota for and profiting from the increased volume of opioid sales in the United States. The Opioid Supply Chain Enterprise is an association-in-fact enterprise within the meaning of § 1961. The Opioid Supply Chain Enterprise consists of the RICO Supply Chain Participants.

508. The RICO Supply Chain Participants were members of the HDA. Each of the RICO Supply Chain Participants is a member, participant, and/or sponsor of the HDA, and has been since at least 2006. Each Supply Chain Defendant utilized the HDA to form the interpersonal relationships of the Opioid Supply Chain Enterprise and to assist them in engaging in the pattern of racketeering activity that gives rise to the Count. 860. At all relevant times, the Opioid Supply Chain Enterprise: (a) had an existence separate and distinct from each of the RICO Supply Chain Participants; (b) was separate and distinct from the pattern of racketeering in which the RICO Supply Chain Participants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the RICO Supply Chain Participants; (d) was characterized by interpersonal relationships among the RICO Supply Chain Participants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. Each member of the Opioid Supply Chain Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid quotas and resulting sales.

509. The RICO Supply Chain Participants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public by knowingly conducting or participating in the conduct of the Opioid Supply Chain Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

510. The RICO Supply Chain Participants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts

of racketeering activity that the RICO Supply Chain Participants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Supply Chain Participants' regular use of the facilities, services, distribution channels, and employees of the Opioid Supply Chain Enterprise. The RICO Supply Chain Participants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

511. The RICO Supply Chain Participants also conducted and participated in the conduct of the affairs of the Opioid Supply Chain Enterprise through a pattern of racketeering activity by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

512. The RICO Supply Chain Participants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 843(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of § 843(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 843(d)(1).

513. Each of the RICO Supply Chain Participants is a registrant as defined in the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

514. The RICO Supply Chain Participants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a. Mail Fraud: The RICO Supply Chain Participants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

b. Wire Fraud: The RICO Supply Chain Participants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

c. Controlled Substance Violations: The RICO Supply Chain Participants violated 21 U.S.C. § 843 by knowingly or intentionally furnishing false or fraudulent information in, and/or omitting material information from, documents filed with the DEA.

515. The RICO Supply Chain Participants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

516. The RICO Supply Chain Participants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

517. The RICO Supply Chain Participants hid from the general public and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities about the reality of the suspicious orders that the RICO Supply Chain Participants were filling on a daily basis – leading to the diversion of hundreds of millions of doses of prescriptions opioids into the illicit market.

518. The RICO Supply Chain Participants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing

prescription opioids.

519. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding manufacturing prescription opioids and refusing to report suspicious orders.

520. As described herein, the RICO Supply Chain Participants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

521. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiff's business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Supply Chain Participants. The predicate acts were committed or caused to be committed by the RICO Supply Chain Participants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

522. The pattern of racketeering activity alleged herein and the Opioid Supply Chain Enterprise are separate and distinct from each other. Likewise, the RICO Supply Chain Participants are distinct from the enterprise. 875. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court. 876. Many of the precise dates of the RICO Supply Chain Participants' criminal actions at issue here have been hidden by Defendants and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Supply Chain Enterprise alleged herein depended upon secrecy.

523. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

524. It was foreseeable to the RICO Supply Chain Participants that Plaintiff would be harmed when they refused to report and halt suspicious orders, because their violation of the duties imposed by the CSA and Code of Federal Regulations allowed the widespread diversion of prescription opioids out of appropriate medical channels and into the illicit drug market – causing the opioid epidemic that the CSA intended to prevent.

525. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

526. The RICO Supply Chain Participants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property. The RICO Supply Chain Participants' pattern of racketeering activity, including their refusal to identify, report and halt suspicious orders of controlled substances, logically, substantially and foreseeably cause an opioid epidemic. Plaintiff was injured by the RICO Supply Chain Participants' pattern of racketeering activity and the opioid epidemic that they created.

527. The RICO Supply Chain Participants knew that the opioids they manufactured and supplied were unsuited to treatment of chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse. Nevertheless, the RICO Supply Chain Participants engaged in a scheme of deception, that utilized the mail and wires as part of their fraud, in order to increase sales of their opioid products by refusing to identify, report suspicious orders of prescription opioids that they knew were highly addictive, subject to abuse, and were actually being diverted into the illegal market.

528. The RICO Supply Chain Participants' predicate acts and pattern of racketeering activity were a cause of the opioid epidemic which has injured Plaintiff in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic.

529. Specifically, Plaintiff's injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include:

a. Losses caused by the decrease in funding available for Plaintiff's public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;

b. Costs for providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;

c. Costs of training emergency and/or first responders in the proper treatment of drug overdoses;

d. Costs associated with providing police officers, firefighters, and emergency and/or first responders with naloxone—an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

e. Costs associated with emergency responses by police officers, firefighters, and emergency and/or first responders to opioid overdoses;

f. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;

g. Costs for providing treatment of infants born with opioid-related medical conditions, or born addicted to opioids due to drug use by mother during pregnancy;

h. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population;

i. Costs associated with increased burden on Plaintiff's judicial system, including increased security, increased staff, and the increased cost of adjudicating criminal matters due to the increase in crime directly resulting

from opioid addiction;

j. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation;

k. Loss of tax revenue due to the decreased efficiency and size of the working population in Plaintiff's Community;

l. Loss of productivity and economic opportunity;

m. Costs associated with extensive clean-up of public parks, spaces, and facilities of needles and other debris and detritus of opioid addiction;

n. Losses caused by diminished property values in neighborhoods where the opioid epidemic has taken root; and

o. Losses caused by diminished property values in the form of decreased business investment and tax revenue. 884. Plaintiff's injuries were proximately caused by Defendants' racketeering activities because they were the logical, substantial and foreseeable cause of Plaintiff's injuries. But for the opioid-addiction epidemic created by Defendants' conduct, Plaintiff would not have lost money or property.

530. Plaintiff's injuries were directly caused by the RICO Supply Chain Participants' pattern of racketeering activities.

531. Plaintiff is most directly harmed and there are no other plaintiffs better suited to seek a remedy for the economic harms at issue here.

532. Plaintiff seeks all legal and equitable relief as allowed by law, including, inter alia, actual damages; treble damages; equitable and/or injunctive relief in the form of court-supervised corrective communication, actions and programs; forfeiture as deemed proper by the Court; attorney's fees; all costs and expenses of suit; and pre- and post-judgment interest, and all of the relief sought into the First Claim for Relief, as the Court deems just and applicable.

THIRD CLAIM FOR RELIEF

PUBLIC NUISANCE

Violations of Arizona Revised Statutes § 13-2917

(Against All Defendants)

533. Bullhead City re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.

534. A.R.S. § 13-2917(A)(1) provides that "[i]t is a public nuisance" for anything "[t]o be injurious to health, indecent, offensive to the senses or an obstruction to the free use of property that interferes with the comfortable enjoyment of life or property by an entire community or neighborhood or by a considerable number of persons."

535. A.R.S. § 13-2917(A) notes that a public nuisance is "no less a nuisance because the extent of the annoyance or damage inflicted is unequal."

536. Bullhead City brings this action under A.R.S. § 13-2917(C) to abate, enjoin, and prevent the public nuisance created by the Defendants.

537. Each Defendant, acting individually and in concert, has created or assisted in the creation of a condition that is injurious to the health and interferes with the comfortable enjoyment of life and property of entire communities or neighborhoods or of any considerable number of persons in Bullhead City in violation of A.R.S. § 13-2917.

538. The public nuisance is substantial and unreasonable. Defendants' actions caused and continue to cause the public health epidemic described above in the County, and that harm outweighs any offsetting benefit.

539. Defendants knew or should have known that their promotion, distribution, and dispensing of opioids was reckless, false and misleading, and that their deceptive marketing scheme and other unlawful, unfair, and fraudulent actions would create or assist in the creation of the public nuisance.

540. Defendants' actions were, at the very least, a substantial factor in opioids becoming widely available and widely used. Defendants' actions were, at the very least, a

substantial factor in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic pain, sabotaging these practitioners' ability to protect their patients from opioid-related injuries and conditions. Without Defendants' actions, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted or much less severe.

541. The public nuisance created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be abated.

542. Pursuant to A.R.S. § 13-2917(C), Bullhead City requests an order providing for abatement of the public nuisance that Defendants created or assisted in the creation of, and enjoining Defendants from future violations A.R.S. § 13-2917.

543. Additionally, as a direct and proximate cause of the public nuisance that Defendants' created, Bullhead City has suffered and will continue to suffer harm, and is entitled to damages in an amount to be determined at trial.

PUNITIVE DAMAGES

544. Plaintiff re-alleges all paragraphs of this Complaint as if set forth fully herein.

545. By engaging in the above-described unfair acts or practices, Defendants acted with actual malice, wantonly, and oppressively. Defendants acted with deliberate and conscious disregard for the rights and safety of others and/or in a reckless, wanton, willful, or gross manner. Defendants acted with a prolonged indifference to the adverse consequences of their actions and/or omissions. Defendants acted with a conscious disregard for the rights and safety of others in a manner that had a great probability of causing substantial harm.

546. Defendants were selling and/or manufacturing dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Thus, Defendants knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than legitimate medical, scientific or industrial channels. Because of the severe level of danger posed by, and indeed visited upon the Plaintiff's Community by, these dangerous drugs, Defendants owed a high duty of care to ensure that these drugs were only

used for proper medical purposes. Defendants chose profit over prudence and the safety of the community, and an award of punitive damages is appropriate as punishment and a deterrence.

547. By engaging in the wrongful conduct described herein above, Defendants engaged in willful misconduct and exhibited an entire want of care that would raise the level of actual malice and/or a conscious, reckless and outrageous indifference to indifference to the health, safety and welfare of the Plaintiff and others.

VI. PRAYER FOR RELIEF

548. Bullhead City prays that the Court issue an order granting all relief requested in this complaint to the fullest extent allowed at law or in equity, including:

1. An Order declaring that Defendants have created a public nuisance in violation of A.R.S. § 13-2917;

2. An Order enjoining Defendants from performing any further acts in violation of A.R.S. § 13-2917;

3. An Order mandating that Defendants abate the public nuisance that they created in Bullhead City in violation of A.R.S. § 13-2917, including the costs of abatement;

4. Actual damages, in an amount to be proven at trial;

5. Treble or multiple damages as allowed by statute;

6. Punitive damages, in an amount to be proven at trial;

7. Exemplary damages, in an amount to be proven at trial;

8. Equitable and injunctive relief in the form of Court-enforced corrective action, programs, and communications;

9. Forfeiture disgorgement, restitution and/or divestiture of proceeds and assets;

10. Attorneys' fees;

11. Costs and expenses of suit;

12. Pre- and post-judgment interest; and

13. Such other and further relief as this Court deems appropriate.

VII. JURY TRIAL DEMAND

Bullhead City demands a trial by jury on all claims and of all issues so triable.

DATED: July 9, 2021 THEODORA ORINGHER PC,

By: */s/ Jeffrey H. Reeves*

THEODORA ORINGHER PC
Jeffrey H. Reeves (CA Bar No. 156648)
jreeves@tocounsel.com
535 Anton Boulevard, Ninth Floor
Costa Mesa, California 92626-7109
Telephone: (714) 549-6200
Facsimile: (714) 549-6201

THEODORA ORINGHER PC
Cheryl Priest Ainsworth (CA Bar No. 255824)
cainsworth@tocounsel.com
1840 Century Park East, Suite 500
Los Angeles, CA 90067
Telephone: (310) 557-2009
Facsimile: (310) 551-0283

FENNEMORE CRAIG, P.C.
J. Christopher Gooch (AZ Bar No. 019101)
John P. Katies (AZ Bar No. 012767)
2394 East Camelback Road, Suite 600
Phoenix, Arizona 85016-9077
Telephone: (602) 916-5000
Facsimile: (602) 916-5999

Attorneys for Plaintiff
Bullhead City, Arizona